NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE MERCK & CO., INC. SECURITIES, DERIVATIVE & "ERISA" LITIGATION	**MDL No. 1658 (SRC)**
THIS DOCUMENT RELATES TO: THE CONSOLIDATED SECURITIES ACTION	**Civil Action No. 05-1151 (SRC)** **Civil Action No. 05-2367 (SRC)** **OPINION**

CHESLER, District Judge

INTRODUCTION

This securities fraud action revolves around rofecoxib, the prescription arthritis medication that had been sold by Defendant Merck & Co., Inc. ("Merck") as Vioxx from May 1999 to September 30, 2004, when it was withdrawn from the market due to safety concerns. Vioxx, a non-steroidal anti-inflammatory drug ("NSAID"), was touted as superior to other NSAIDs, such as aspirin and naproxen, because it did not have adverse gastrointestinal ("GI") side effects. To summarize the drug's relevant mechanism in simple terms: Vioxx worked to relieve pain by selectively inhibiting the COX-2 enzyme without suppressing COX-1, which helps maintain protective GI mucus as well as affects blood clotting. Traditional NSAIDs, in contrast, inhibit both enzymes and are thus associated with adverse GI effects, including serious perforations. The matter before the Court concerns Merck's motion to dismiss the Corrected Consolidated Fifth Amended Class Action Complaint (the "Complaint") pursuant to Federal

Rule of Civil Procedure 12(b)(6).[1]

Plaintiffs in this putative class action are persons and entities who acquired Merck stock between May 21, 2009 and October 29, 2004 (the "Class Period").[2] They maintain that Merck overstated the commercial viability of Vioxx by deliberately, or at the very least recklessly, downplaying the possible link between Vioxx and an increased risk of heart attack or other cardiovascular ("CV") events. According to the Complaint,[3] Merck had evidence strongly indicating a Vioxx-heart attack link even before the product was introduced into the market. The Complaint further alleges that the evidence mounted throughout the Class Period, particularly upon the conclusion of Merck's own large-scale trial known as "VIGOR"[4] in March 2000, which

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[1] Merck's motion is also filed on behalf of various Merck-affiliated individuals named as Defendants. Those individuals are: Raymond V. Gilmartin, Peter S. Kim, Alise S. Reicin, Judy C. Lewent, Kenneth C. Frazier, Richard C. Henriques, Jr., David Anstice, Per Wold-Olsen, Richard T. Clark, Bernard J. Kelley, Lawrence A. Bossidy, William G. Bowen, Johnetta B. Cole, Niall FitzGerald, William B. Harrison, Jr. William N. Kelley, Heidi G. Miller, Thomas E. Shenk, Anne M. Tatlock and Samuel O. Thier. Individual Defendant Edward M. Scolnick separately filed his own motion to dismiss but joins in many of the arguments raised in Merck's papers. For purposes of simplicity, the Court will generally refer to the movant as "Merck" unless the discussion calls for a precise identification of the Defendant at issue.

[2] Plaintiffs' rationale for the extension of the identified Class Period beyond the date on which Vioxx was removed from the market will become evident upon the Court's discussion of loss causation. To preview that discussion, Plaintiffs seek to recover for an alleged corrective disclosure and securities price drop that occurred on November 1, 2004, the first business day following the Class Period end date.

[3] The Complaint serves as the source of the many facts discussed and relied upon by the Rule 12(b)(6) analysis conducted by the Court. The Court wishes to make clear, at the outset of this Opinion, that the factual allegations of the Complaint are assumed to be true only for purposes of evaluating whether the legal claims for relief meet the pleading standards, whether they be those imposed by Federal Rule of Civil Procedure 8(a) or some heightened pleading requirement. Nothing in this Opinion should be construed as a finding by the Court that an alleged fact has been established.

[4] This acronym stands for Vioxx Gastrointestinal Outcomes Research.

compared GI outcomes for users of Vioxx versus naproxen. Yet, throughout the Class Period, Merck stood behind the safety of Vioxx and reassured the public that, in its view, Vioxx was not prothrombotic but rather naproxen was cardioprotective. Plaintiffs contend that Merck's misstatements of fact and belief regarding its purported "blockbuster" drug Vioxx artificially inflated the stock price, the value of which fell sharply when the truth about Vioxx's safety profile began to emerge.

PROCEDURAL HISTORY

The procedural history of this case preceding this motion is significant and bears recounting. Upon Merck's earlier motion, this Court had dismissed the Corrected Consolidated Fourth Amended Class Action Complaint as time-barred. On Plaintiffs' appeal of this Court's April 12, 2007 Order of dismissal, the Third Circuit reversed this Court's ruling and thereafter issued its mandate remanding the matter on October 27, 2008. On remand to this Court, Plaintiffs filed the instant Complaint on March 10, 2009, and Defendants moved to dismiss it on or about May 1, 2009. Shortly thereafter, the Supreme Court granted Defendants' petition for a writ of certiorari seeking review of the Third Circuit's ruling on the statute of limitations issue. Upon stipulation by the parties, this Court stayed proceedings in the district court pending adjudication of the appeal before the Supreme Court. On April 27, 2010, the Supreme Court affirmed the Third Circuit's decision. Accordingly, the stay of this action was lifted, and the parties proceeded to complete briefing on the instant motion to dismiss.

Similar to the previous pleading, the currently operative Complaint in this multi-districted securities class action contains six counts, asserting various claims under the Securities Exchange

Act of 1934 ("Exchange Act"), 15 U.S.C. 78a, et seq., (2000), and the Securities Act of 1933 ("Securities Act"), 15 U.S.C. 77a, et seq., (2000). The factual background has been set forth at length in the three opinions issued in connection with the earlier motion to dismiss. As the Court writes for the parties only, it will not repeat the narrative here.

STANDARD OF REVIEW

The issue before the Court on a Rule 12(b)(6) motion to dismiss "is not whether plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence in support of the claims." In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1420 (3d Cir. 1997) (quoting Scheuer v. Rhodes, 416 U.S. 232, 236 (1974)). To make that determination, the Court must employ the standard of review articulated by the Supreme Court in Bell Atlantic Corp. v. Twombly and Ashcroft v. Iqbal. A complaint will survive a motion under Rule 12(b)(6) only if it states "sufficient factual allegations, accepted as true, to 'state a claim for relief that is plausible on its face.'" Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009) (quoting Bell Atlantic v. Twombly, 550 U.S. 544, 570 (2007)). The plausibility standard will be met if the complaint "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. (citing Twombly, 550 U.S. at 556.) While the complaint need not demonstrate that a defendant is *probably* liable for the wrongdoing to meet the pleading standard of Federal Rule of Civil Procedure 8(a), allegations that give rise to the mere *possibility* of unlawful conduct will not do. Iqbal, 129 S.Ct. at 1949; Twombly, 550 U.S. at 557.

This case, of course, is a securities fraud action. The Private Securities Litigation Reform Act of 1995 ("PSLRA") imposes certain heightened pleading requirements on claims brought

pursuant to Exchange Act § 10(b) and the statute's implementing regulation Securities and Exchange Commission ("SEC") Rule 10b-5, and these will be set forth below in the discussion of Plaintiffs' Rule 10b-5 claim. Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 320-21 (2007) (noting that prior to the enactment of the PSLRA, the pleading standard of Rule 9(b) governed the sufficiency of a complaint for securities fraud). Apart from the requirements of the PSLRA made specifically applicable to certain claims under the Exchange Act, the pleading standard is heightened by Federal Rule of Civil Procedure 9(b) insofar as any claim is based on allegations of fraudulent conduct. In re Suprema Specialties, Inc. Sec. Litig., 438 F.3d 256, 270 (3d Cir. 2006) (holding that when acts of fraud form the basis of a Securities Act claim, the sufficiency of the claim must be evaluated under Rule 9(b)); Burlington Coat Factory, 114 F.3d at 1417 (holding that Rule 9(b) has been "rigorously applied in securities fraud cases"). Rule 9(b) requires plaintiffs to plead "the circumstances constituting the fraud . . . with particularity." Fed.R.Civ.P. 9(b); see also Tellabs, 551 U.S. at 320 (noting that prior to the enactment of the PSLRA, the pleading standard of Rule 9(b) governed the sufficiency of a complaint for securities fraud).

In evaluating a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court must consider the complaint in its entirety. Tellabs, 551 U.S. at 322. It is also proper to consider "documents incorporated into the complaint by reference, and matters of which the court may take judicial notice." Id.

ANALYSIS

I. Scope of Wrongdoing On Which Plaintiffs Base Their Claims: Defendants' Judicial Estoppel Argument

Before engaging in an analysis of the Complaint's factual allegations vis-a-vis the elements of the various Exchange Act and Securities Act claims asserted, the Court must first resolve a dispute between the parties as to what wrongdoing properly underlies Plaintiffs' claims. In their brief, Plaintiffs identify three categories of statements and omissions as giving rise to their claim: (1) misrepresentations concerning the safety profile of Vioxx; (2) misleading characterization of Merck's espousal of the naproxen hypothesis; and (3) misrepresentations regarding lack of internal data at Merck indicating that Vioxx was prothrombotic. Defendants argue that the doctrine of judicial estoppel bars Plaintiffs from proceeding on any predicate other than their allegation that Merck falsely presented the naproxen hypothesis as its opinion concerning the VIGOR results.

The Court holds that Plaintiffs' claim will not be limited based on judicial estoppel. The doctrine of judicial estoppel applies only where a litigant has taken a legal position that is "clearly inconsistent" with an earlier position, has succeeded in persuading a court in accepting the earlier position and has or would derive an unfair advantage from having courts accept the inconsistent positions. New Hampshire v. Maine, 532 U.S. 742, 750 (2001). Judicial estoppel focuses on preserving the integrity of the judicial system, as opposed to the relationship between parties. Delgrosso v. Spang and Co., 903 F.2d 234, 241 (3d Cir. 1990). Thus, the Supreme Court has observed that "[a]bsent success in a prior proceeding, a party's later inconsistent position introduces no risk of inconsistent court determinations and thus poses little threat to

judicial integrity." New Hampshire v. Maine, 532 U.S. at 750-51 (internal quotation and citation omitted). For the reasons that follow, the Court concludes that it has not been presented with a situation which threatens the integrity of the judicial system and which warrants finding Plaintiffs estopped from seeking relief for any of the alleged misrepresentations and omissions alleged in the Complaint. In other words, the Court will evaluate the sufficiency of the Complaint on its merits and permit the claims to surmount this Rule 12(b)(6) motion assuming the factual allegations of the Complaint properly and adequately plead violations of Rule 10b-5 and other securities laws.

At oral argument, Merck stressed the disingenuous nature of Plaintiffs' "pivot and turn" maneuver. (See, e.g., 7/12/11 Tr. at 91-93.) According to Merck, Plaintiffs succeeded in rehabilitating their time-barred action by making an appellate argument that altered or, at the very least, truncated the securities fraud claim to consist of Merck's allegedly falsely held belief in the naproxen hypothesis, then returned to the district court to litigate their action alleging misrepresentation of belief *and* fact. Merck maintains that to accept Plaintiffs' current inconsistent position that the claim does in fact impugn Merck's representations of fact as to Vioxx's CV safety profile, not just its opinion statements, would allow Plaintiffs to benefit unfairly from molding their claims and theories depending on the exigencies and/or opportunities at a given stage of the litigation.

Merck correctly points out that on appeal, Plaintiffs argued that the district court had evaluated the timeliness of Plaintiffs' claim based on its misunderstanding of their theory of wrongdoing. In particular, Plaintiffs took the position that the gravamen of their fraud claim is that Merck misled investors by proffering an opinion (the naproxen hypothesis) that it did not

honestly hold. In contrast, the district court had "analyzed whether Merck misrepresented the fact that the results of the VIGOR study could support multiple hypotheses (i.e., that naproxen lowers the risk of CV events or that Vioxx raises the risk)." In re Merck, 543 F.3d 150, 166 (3d Cir. 2008). It is clear from the Third Circuit's published opinion deciding the appeal that its analysis of the issue before it – the timeliness of Plaintiffs' securities fraud claim under the inquiry notice standard of accrual – was indeed based on its conclusion that the gravamen of the fraud claim consisted of Merck's misrepresentation that it believed in the naproxen hypothesis. Merck, 543 F.3d at 167. It held that the "asserted basis of [Plaintiffs'] claims is that Merck defrauded investors by proposing and reasserting the naproxen hypothesis at the same time that it knew the hypothesis was false." Id. Thus identifying the claim at issue, the Court of Appeals applied the then-valid inquiry notice standard of determining when the claim accrued. It held that the district court incorrectly concluded that Plaintiffs were on inquiry notice on or before October 9, 2001 because, as of that date, there was no indication (or "storm warnings") that Merck did not believe the naproxen hypothesis. Id. at 172.

Notwithstanding Merck's argument that Plaintiffs prevailed on appeal by shifting the gravamen of their claim, the Court does not discern that Plaintiffs have taken a "clearly inconsistent" position in crafting and pursuing the currently operative Complaint. The gravamen of the Complaint's securities fraud claims is, indeed, the allegedly fraudulent presentation by Merck of the naproxen hypothesis as its opinion concerning adverse CV event data. It continues to form the core of the securities fraud action before the Court. Merck has tried, unsuccessfully, to persuade the Court that by emphasizing the opinion-based gravamen of the wrongdoing alleged, Plaintiffs should be understood to have represented to the Court of Appeals that Merck's

statement of belief in the naproxen hypothesis constituted the *exclusive* basis of their claims. Alleged misrepresentations by Merck about Vioxx's CV safety, including those made even before the VIGOR results were available, were at issue in the Fourth Amended Complaint, just as they are in the instant Complaint. Plaintiffs argued on appeal that this Court misread the Fourth Amended Complaint to challenge Merck's promotion of the naproxen hypothesis as proven fact rather than as what the company thought was the more likely explanation for VIGOR's negative CV data. Merck, in essence, urges this Court to interpret that position as an abandonment of their fact-based claims, but there is no reason to construe Plaintiffs' appellate arguments regarding the nature of the alleged naproxen hypothesis misrepresentation as a repudiation of other statements Plaintiffs claimed violated securities fraud laws.

Moreover, Merck's judicial estoppel argument engages in little to no substantive analysis of the Supreme Court's opinion concerning the timeliness of Plaintiffs' Rule 10b-5 claim. Plaintiffs did not ultimately prevail in their appeal on grounds that the district court had mischaracterized what was actionable about Merck's naproxen hypothesis statements. The Supreme Court reviewed the Court of Appeals' decision on writ of certiorari, and though it affirmed the ruling that Plaintiffs' claim was not time-barred, it did so on markedly different grounds. The Supreme Court adopted the Third Circuit's characterization of the claim as challenging Merck's false representation of its belief in the naproxen hypothesis. In re Merck, 130 S.Ct. 1784, 1792 (2010). However, its statute of limitations analysis was not concerned with whether or not Plaintiffs were on inquiry notice as to Merck's alleged lack of belief in the naproxen hypothesis. The Supreme Court essentially rejected the inquiry notice standard underpinning the Third Circuit's analysis of the timeliness of Plaintiffs' securities fraud claim. It

concluded that the limitations period for a securities fraud claim is not initiated when a plaintiff is on inquiry notice of either a defendant's intent or the facts underlying the misrepresentation. Id. at 1797-98. Rather, it explicitly held that a securities fraud claim does not accrue until a "plaintiff discovers or a reasonably diligent plaintiff would have discovered 'the facts constituting the violation' including scienter – irrespective of whether the actual plaintiff undertook a reasonably diligent investigation." Id. at 1798.

Considering the crux of the Supreme Court's decision – which applied the discovery rule of § 1658(b)(1) to Rule 10b-5 securities fraud claims and held that "the facts constituting the violation" necessarily entails discovery of facts relating to scienter, an essential element of the violation – it cannot be said that Plaintiffs derived a benefit from their position that Merck's wrongdoing consisted of its promotion of a false belief. The Supreme Court concluded that, in the context of claims under Exchange Act Section 10(b), the entire concept of inquiry notice (applied by the district court and by the Third Circuit on appeal) at most served as a starting point for determining when a diligent plaintiff would have commenced an investigation, not the point at which the plaintiff did discover or would have discovered the facts constituting the violation. The Supreme Court's ultimate resolution of the statute of limitations issue turned not on any particular litigation theory espoused by Plaintiffs but rather on the point at which any securities fraud claim may be deemed to have ripened. Regardless of the accurate characterization of Plaintiffs' securities fraud claim, the standard adopted by the Supreme Court had not been applied by either this Court or the Court of Appeals in considering the timeliness of the claim. Had the appeal of this Court's April 12, 2007 Order of dismissal concluded with the Court of Appeals' reversal of that decision, Merck might very well have had a much stronger argument for

holding Plaintiffs estopped from seeking relief for any alleged act of securities fraud other than the claim as depicted before the Third Circuit. Even so, however, the Court would have approached the question with restraint, given its doubts that Plaintiffs have taken inconsistent positions.

Restraint is, indeed, always the prudent course when considering whether to apply judicial estoppel, given its punitive nature. The Third Circuit has been clear that judicial estoppel is a harsh sanction, which the Court should not impose unless other, less drastic measures are inadequate to address a party's misconduct. Klein v. Stahl GMBH & Co. Maschinefabrik, 185 F.3d 98, 108-110 (3d Cir. 1999). The doctrine should not be invoked solely because a party has taken positions that are irreconcilably inconsistent; rather, "judicial estoppel is unwarranted unless the party changed his or her position 'in bad faith – i.e., with intent to play fast and loose with the court.'" Krystal Cadillac-Oldsmobile GMC Truck, Inc. v. Gen. Motors Corp., 337 F.3d 314, 319 (3d Cir. 2003) (quoting Montrose Medical Group Participating Savings Plan v. Bulger, 243 F.3d 773, 779 (3d Cir. 2001)); see also Klein, 185 F.3d at 111 (stressing that application of judicial estoppel sanction requires, at a minimum, a district court to find both inconsistency and bad faith). Here, the Court's exercise of its inherent sanctioning power would simply not be a fitting remedy. The Court sees no evidence of bad faith by Plaintiffs. It has not been persuaded that Plaintiffs' litigation strategy has threatened the integrity of the judicial system or otherwise been implemented to gain unfair advantage.

The Court, in short, will not preclude Plaintiffs from seeking a determination of the claims pled on their merits when the threshold requirements justifying judicial estoppel have not been met.

II. Exchange Act Securities Fraud Claim

Under Section 10(b) of the Exchange Act, a person or entity may not "use or employ, in connection with the purchase or sale of any security, . . . any manipulative or deceptive device or contrivance in contravention of [SEC] rules and regulations." 15 U.S.C. § 78j(b). SEC Rule 10b-5(b), in turn, makes it unlawful to "make any untrue statement of material fact or to omit to state a material fact in order to make the statements made, in light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b). A private cause of action for damages sustained as the result of a violation of Section 10(b) and Rule 10b-5 requires the plaintiff to establish the following six elements:

> (1) a material misrepresentation or omission;
>
> (2) scienter, i.e., a wrongful state of mind;
>
> (3) a connection with the purchase or sale of a security;
>
> (4) reliance, also known as "transaction causation" in cases involving public securities markets;
>
> (5) economic loss; and
>
> (6) loss causation, i.e., a causal connection between the material misrepresentation and the loss.

Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 341-42 (2005); see also McCabe v. Ernst & Young, LLP, 494 F.3d 418, 424 (3d Cir. 2007).

The PSLRA imposes heightened pleading requirements on the first and second elements identified above. To survive a motion to dismiss, the complaint must (1) "specify each

statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed" and (2) "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. §§ 78u-4(b)(1) & (2); 15 U.S.C. § 78u-4(b)(3)(2) ("In any private action arising under this chapter, the court shall, on the motion of any defendant, dismiss the complaint if the requirements of [15 U.S.C. §§ 78u-4(b)(1) & (2)] are not met.").

Merck's motion challenges the sufficiency of the securities fraud claim as to the pleading of a material misrepresentation or omission, scienter, loss causation and reliance. Each of these elements will be analyzed in turn.

A. Material Misrepresentation or Omission

To violate Rule 10b-5, a statement or omission must be *"misleading* as to a *material* fact." Basic, Inc. v. Levinson, 485 U.S. 224, 238 (1988) (emphasis in original). A misrepresentation or omission is material if there is a "substantial likelihood that the disclosure . . . would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." Id. at 231-32 (quoting TSC Industries, Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976)). This action involves numerous statements and omissions made by Merck about Vioxx spanning a period of over five years. They are set forth in the Complaint in paragraphs 223 through 380. For purposes of this analysis concerning whether the first element of a Rule10b-5 claim is satisfied, it is not necessary to identify each allegedly offending

statement. Rather, to assist the Court in evaluating whether the statements or non-disclosures are actionable, Plaintiffs divide the allegedly misleading statements and omissions into three categories.

The first group consists of a number of promotional statements made by Merck about Vioxx in the time period commencing on May 21, 1999, when Merck announced Food and Drug Administration ("FDA") approval of the drug, to March 2000, immediately prior to the announcement of the VIGOR trial results. These "Pre-VIGOR" statements generally touted Vioxx's strong commercial performance as a result of, among other things, its "exceptional product profile" (January 26, 2000 press release) and "product profile for . . . safety" (March 22, 2000 press release). (Compl., ¶¶ 237, 240.) Other statements, including the May 21, 1999 press release announcing FDA approval, stated that the "most common side effects reported in clinical trial with VIOXX were upper respiratory infection, diarrhea and nausea." (Id., ¶ 223.)

The second group consists of statements made beginning on March 27, 2000, when the VIGOR results were publicized, through August 2004, that is, just prior to the withdrawal of Vioxx from the market. The VIGOR study, as extensively discussed in previous opinions, was Merck's large GI outcomes clinical trial which demonstrated that patients taking Vioxx experienced four times as many heart attacks and other adverse CV events than patients taking naproxen. Merck's March 27, 2000 press release announcing these results attributed them to the purported cardioprotective property of naproxen. In relevant part, the press release stated:

> In addition, significantly fewer thromboembolic events were observed in patients taking naproxen in this GI outcomes study, which is consistent with naproxen's ability to block platelet aggregation. This effect on these events had not been observed previously in any clinical studies for naproxen. VIOXX, like all COX-2 selective medicines, does not block

> platelet aggregation and therefore would not be expected to have similar effects.
>
> * * *
>
> An extensive review of safety data from all other completed and ongoing clinical trials, as well as the post-marketing experience with VIOXX, showed no indication of a difference in the incidence of thromboembolic events between VIOXX, placebo and comparator NSAIDs. Further analyses are ongoing, and final results of the GI outcomes study with VIOXX will be presented at peer-reviewed medical meetings this year.

(Id., ¶ 244.)

The Complaint alleges that these statements and variations thereof were reiterated by Merck throughout the time period from the announcement of the VIGOR results to the withdrawal of Vioxx. These statements were made in SEC filings, press releases and remarks quoted in news publications. For example, an April 10, 2001 press release expressed Merck's confidence "in the comprehensive data that support the excellent gastrointestinal and overall safety profile of VIOXX." (Id., ¶ 280.) A May 29, 2001 press release stated: "In response to news and analyst reports of data the Company first released a year ago, Merck & Co., Inc. today reconfirmed the favorable cardiovascular safety profile of VIOXX." (Id., ¶ 286.) Defendant Scolnick, then President of Merck Research Laboratories, was quoted in an October 9, 2001 *New York Times* article as stating, with regard to the two acknowledged interpretations of the VIGOR study's CV results, that "It [Merck] found no evidence that Vioxx increased the risk of heart attacks" and that "the likeliest interpretation of that data is that naproxen lowered the thrombotic event rate." (Id., ¶ 302.) On November 5, 2003, the *Wall Street Journal* published a letter written by Defendant Kim, Scolnick's successor, responding to an article reporting on adverse CV findings made in a non-Merck study and reaffirming Merck's belief in the safety of Vioxx.

That letter criticized the study producing the adverse data and stated, among other things, as follows:

> Merck stands behind the safety of Vioxx based on the results of numerous randomized, controlled clinical trials.
>
> Finally, it should be noted that Merck has previously announced it is conducting large prospective, randomized placebo-controlled clinical trials that, when added to the extensive data from clinical trials already available, will provide an even more comprehensive picture of the cardiovascular safety profile of Vioxx.

(Id., ¶ 358.) As late as August 2004, just over a month before Vioxx was withdrawn from the market for its increased risk for CV events, Merck was reassuring the market of the drug's safety. On August 25, 2004, Bloomberg News reported the results of a study conducted by Kaiser Permanente, which found that there was a statistically significant difference in heart attack risk between users of Vioxx and users of Celebrex. (Hereinafter, the Court will refer to the study as the "Kaiser Study.") The next day, Merck issued a public statement criticizing the Kaiser study, noting that Merck "strongly disagrees" with its conclusions and stating: "Based on all of the data that are available from our clinical trials, Merck stands behind the efficacy and safety, including cardiovascular safety, of VIOXX." (Id., ¶ 374.)

The third group of alleged misrepresentations consists of statements made on September 30, 2004 concerning Vioxx's withdrawal from the worldwide market on that date. Plaintiffs allege that Merck was forced to withdraw the drug abruptly upon the recommendation of an External Safety Monitoring Board ("ESMB") overseeing the APPROVe study, another Vioxx clinical trial. According to the Complaint, APPROVe data again showed an increased risk of adverse CV events in patients taking Vioxx. Merck's Chief Executive Officer Gilmartin made a

number of statements in connection with the withdrawal, including that it "would have been possible to continue to market Vioxx with labeling that would incorporate the new data" and that the APPROVe study's adverse CV data "was totally unexpected." (Id., ¶ 379.)

1. The Pre-VIGOR Statements

The Court finds that many of the pre-VIGOR statements as alleged constitute actionable misrepresentations.[5] Plaintiffs maintain that in making these statements, Merck introduced the

[5] The Court notes that some of the representations alleged in the Complaint to be misleading and in violation of Rule 10b-5 concern statements that do not regard Vioxx's CV safety profile. Both before and after the conclusion of the VIGOR trial, Merck made assertions about the drug's popularity or its generation of revenue for Merck. To cite one example, an attachment to Merck's December 12, 2000 Form 8-K quotes Defendant Gilmartin as stating:

> VIOXX has achieved approximately 50 percent of the new prescriptions in the COX-2 class in the U.S. Combined with its strong leadership in Europe, VIOXX is firmly positioned for outstanding worldwide growth . . . . Since its extraordinarily successful launch last year, VIOXX, Merck's once-a-day medicine for osteoarthritis and for acute pain, has become the world's fastest growing prescription arthritis medicine. Among its unique advantages, VIOXX is the only COX-2 indicated [drug] in the U.S. both for osteoarthritis and acute pain, such as pain following knee or hip replacement and dental surgery.

(Compl., ¶ 271.) To cite another example, Merck's 2002 Annual Report, issued on March 24, 2003, read as follows:

> Vioxx, Merck's once-a-day coxib, remains the largest and most prescribed arthritis pain medication across many markets worldwide, including Europe, Canada and Latin America. For this year, Vioxx sales grew 8% over 2001, achieving $2.5 billion in sales[.] [I]n 2003, worldwide sales of VIOXX and Arcoxia are expected to be approximately $2.6 billion to $2.8 billion.

(Id., ¶ 345.) Though Plaintiffs challenge such statements as materially false and misleading, hornbook securities fraud law holds that present statements of fact that were accurate at the time they were made or which did not require further disclosure to render them accurate are not actionable. See, e.g., Oran v. Stafford, 226 F.3d 275, 286 (3d Cir. 2000) (holding that in the absence of a misleading or incomplete prior disclosure, there is no duty to disclose updated corrective information); In re Advanta Corp. Sec. Litig., 180 F.3d 525, 538-39 (3d Cir. 1999)

subject of Vioxx's safety profile and then violated its duty to speak fully and truthfully on that subject by failing to disclose material information suggesting a link between Vioxx and increased CV events. Plaintiffs' theory of liability finds support in securities fraud jurisprudence. See Oran, 226 F.3d at 286 (holding that under securities laws, there is an affirmative duty to disclose when there has been an "inaccurate, incomplete, or misleading prior disclosure."); In re Bristol-Myers Squibb Sec. Litig., 2005 U.S. Dist. LEXIS 18448, at *63 (D.N.J. Aug. 6, 2005). "Some statements, although literally accurate, can become through their context and manner of presentation, devices which mislead investors. For that reason, the disclosure required by the securities laws is measured not by literal truth but by the ability of the material to accurately inform rather than mislead prospective buyers." McMahon & Co. v. Wherehouse Ent't, 900 F.2d 576, 579 (2d Cir. 1990). Once a defendant makes an affirmative statement or characterization about its business, it puts that subject "in play" and assumes a duty, under the securities laws, to speak truthfully about that subject. Shapiro v. UJB Fin. Corp., 964 F.2d 272, 282 (3d Cir.1992), rehearing en banc denied, July 7, 1992; cf. Matrixx Initiatives, Inc. v. Siracusano, 131 S.Ct. 1309, 1322 (2011) (noting that "companies can control what they have to disclose under [§ 10(b) and Rule 10b-5(b)] by controlling what they say to the market.").

(holding that accurate reports of past earnings and general statements of optimism for the future are not actionable).

Merck has not moved to dismiss the Rule 10b-5 claim, or any portion thereof, on grounds that the claim is based on statements that do not bear on Vioxx's safety profile. The Court therefore need not express an opinion at this time on the actionability of such statements. Nevertheless, the Court considers it important to note the breadth of misrepresentations set forth in the Complaint. Its holding and analysis with regard to the sufficiency of the securities fraud claim, based on both pre- and post-VIGOR statements, are limited to the statements discussed and the matters raised by the parties.

The Pre-VIGOR statements, Plaintiffs argue, were rendered misleading in that they would appear to a reasonable investor to reveal complete information about the subject of Vioxx's safety and side effects yet were not truthful in light of undisclosed, negative information in Merck's possession. In particular, Plaintiffs point to an internal analysis from February 1998 comparing the incidence of serious CV problems in patients taking Vioxx in a clinical osteoarthritis trial to patients taking a placebo in other non-Vioxx related large clinical trials conducted by Merck (hereinafter, the "February 1998 Analysis"). The February 1998 Analysis observed an increased risk of serious adverse CV events in trial participants taking Vioxx as compared to a placebo, with a greater than double risk in female participants. (Compl., ¶ 117.) In pleading that pre-VIGOR statements as to Vioxx's safety were materially misleading, Plaintiffs also point to numerous internal communications at Merck discussing as early as 1997 a concern about the possible prothrombotic qualities of Vioxx, based on data gathered in 1996's Protocol 023 study. According to the Complaint, that data indicated that the selective inhibition of the COX-2 enzyme (the mechanism by which Vioxx alleviated inflammation without adverse GI effects) upset the body's natural balance between prostacyclin (a chemical which inhibits clotting) and thromboxane (a chemical which promotes clots). (Id., ¶¶ 98-114.) Plaintiffs aver that the discussions reflect that based on Protocol 023's implications, Merck decided to postpone a large-scale clinical trial to study GI outcomes of Vioxx until after FDA approval, fearing that the study might confirm a Vioxx-heart attack link and "kill the drug." (Id., ¶¶ 104-110.)

Under well-established securities fraud jurisprudence, the question the Court must ask is whether the information Merck failed to disclose was material, that is, whether there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the

reasonable investor as having significantly altered the 'total mix' of information made available." Matrixx, 131 S.Ct. at 1318 (quoting Basic, 485 U.S. at 231-32). Relying on the Third Circuit's opinion in Oran, Merck has argued that undisclosed information about the possibility of a link between Vioxx and thrombotic events, as indicated by Protocol 023, the hypothesis concerning the prostaclycin-thromboxane imbalance, and the February 1998 Analysis, cannot as a matter of law be considered material because the information did not conclusively establish a causal connection between the drug and such adverse effects. See Oran, 226 F.3d at 283-84. Oran, however, addressed a situation in which the defendant drug company had not made affirmative mischaracterizations about the safety of its product, but rather made an accurate assertion that the FDA had found that it had an "acceptable safety profile." Id. at 285. Thus, the Oran court concluded that the defendant did not have an affirmative duty to disclose to investors data from adverse events reports suggesting a link between the drug and heart valve disorders. Id. at 283-85. Here, Plaintiffs have alleged that Merck's positive statements about Vioxx's commerical success in light of its "exceptional safety profile" were misleading for failure to completely and accurately represent information known to Merck about the drug. Moreover, insofar as Oran concluded that the withheld information was immaterial as a matter of law because it failed to show a statistically significant risk of an adverse effect on heart valve health, it is factually distinct from this case, in which the non-disclosed information goes beyond adverse event reports. The Court recognizes that, indeed, mere adverse event data does not necessarily alter the total mix of information about the drug's safety, as such information by itself does not shed light on whether the drug in question is causing the event. Matrixx, 131 S.Ct. at 1321. However, Merck's position – that the lack of data supporting a conclusive link between Vioxx and heart

attacks precludes the undisclosed information from meeting the materiality standard – is belied by the Supreme Court's recent discussion of materiality in Matrixx.

Like the case at bar, Matrixx was a securities fraud class action arising from an alleged failure to disclose material information regarding a possible link between a pharmaceutical cold remedy, Zicam, and anosmia, a condition in which the user loses his sense of smell. Id. at 1313. The Court rejected the defendant's argument that, given the absence of information showing a statistically significant incidence of the adverse event, the undisclosed adverse events reports categorically could not be considered material to investors. Id. at 1318-19. The Court stressed the fact-intensive, contextual inquiry that underlies the materiality standard, noting that in some cases "reasonable investors would have viewed reports of adverse events as material even though the reports did not provide statically significant evidence of a causal link." Id. at 1321. It further emphasized that whether non-disclosure was actionable under the securities laws was also very much a function of what information a company had chosen to communicate to the market. The Court reasoned that § 10(b) and Rule 10b-5(b) require disclosure "only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" Id. (quoting 17 C.F.R. § 240.10b-5(b)). Applying these principles and Basic's total mix standard, the Matrixx court held that plaintiffs had adequately pleaded materiality because the withheld information – which consisted mainly of reports from medical professionals concerning patients who had lost their sense of smell as well as a study based on those findings – plausibly indicated a reliable causal link between Zicam and anosmia. Id. at 1322. The Court found that assuming the facts of the complaint to be true, a reasonable investor would have

viewed this information as having altered the total mix of information available in light of the pharmaceutical company's representations to the market that revenues were going to rise even though it had "information indicating a significant risk to its leading revenue-generating product." Id. at 1323. Moreover, the Court noted that the defendant company had publicly declared the safety of its product to be well-established, but it "had evidence of a biological link between Zicam's key ingredient and anosmia, and it had not conducted any studies of its own to disprove that link." Id.

Here, this Court must likewise conclude that the Complaint alleges a material misrepresentation as to the pre-VIGOR statements promoting Vioxx as safe. As alleged, Merck made such statements in spite of information from its own internal analyses that patients taking Vioxx versus a placebo experienced a greater incidence of adverse CV events. The Complaint further avers that the data in particular showed that women taking Vioxx had more than twice as many CV events than women in the placebo group, a statistically significant increase. Reading them together, the factual allegations reflect that Merck also had a serious concern about a possible causal relationship between Vioxx and CV events based on the prostacyclin-thromboxane imbalance data gathered in a clinical trial it performed prior to FDA-approval of the drug. The Complaint sets forth numerous communications about evidence that Vioxx might be prothrombotic and the deliberate and/or reckless failure to explore such a connection.

According to the Complaint, in the fall of 1997, Merck scientists Dr. Alan Nies (in charge of Vioxx's development) and Dr. Barry Gertz (an author of the article reporting on Protocol 023's results) sought the advice of Dr. John Oates, an expert on prostacyclin and thromboxane,

regarding the Protocol 023 data. Plaintiffs aver that, rather than assuage Merck's concerns, Dr. Oates's opinion further supported the conclusions reached by Protocol 023 researchers – that the observed data could not be attributed to an effect Vioxx was having solely on the kidneys and that there was a possibility that Vioxx's selective COX-2 inhibition decreased biosynthesis of prostacyclin and thus disturbed homeostasis with clot-promoting thromboxane, enhancing the risk of heart attack or cardiac arrest. Plaintiffs allege that both Dr. Oates and Merck's own Board of Scientific Advisors urged further study to analyze coronary and cerebrovascular events from the clinical trials of Vioxx. They also allege that Merck did not conduct any further study at that time to disprove the suspected link but rather moved forward with its New Drug Application for Vioxx without disclosing its concern that Vioxx had the potential to cause thrombotic events or the internal data fueling those concerns.

The Complaint additionally avers that, even before consulting Dr. Oates, that is, based solely on the internally-circulated Protocol 023 data and conclusions, Merck deliberately deferred conducting a large-scale trial of GI outcomes, which would compare Vioxx and a traditional NSAID, for fear that it would show a greater incidence of adverse CV events in Vioxx users. One internal email exchange from February 1997 concerning the challenges of designing a GI outcomes trial in light of the Protocol 023 data is demonstrative. In that exchange, a senior research and development executive writes:

> [I] [w]ould allow low dose aspirin - I know this has been discussed to death but real world is everyone is on it so why exclude ***AND without COX-1 inhibition [provided by aspirin] you will get more thrombotic events and kill [the] drug.***

Defendant Reicin, the Executive Director of Clinical Research at Merck Research Laboratories, responds as follows:

> Low Dose Aspirin - I HEAR YOU! This is a no-win situation! The relative risk of [more adverse GI events if we allow] even low dose aspirin may be as high as 2-4 fold. ***Yet, the possibility of increased CV [cardiovascular] events is of great concern- (I just can't wait to be the one to present those results to senior management!)***

(Compl., ¶¶ 105, 107.)[6]

Reicin and the other participants in the email conversation appear to be discussing how to structure a trial that achieves the aim of demonstrating Vioxx's superior GI profile compared to traditional NSAIDs without exposing the potential CV risks of the drug and jeopardizing its commercial viability. The reference to Vioxx's lack of COX-1 inhibition suggests the author's appreciation of the science indicating that selective COX-2 suppression affects the body's metabolism of prostacyclin, causing an excess of thromboxane. The first email quoted indeed expressly states that with a drug that does not inhibit COX-1 - i.e., Vioxx - "you will get more thrombotic events and kill [the] drug." (Id., ¶ 105.) Reicin's response, read in context, likewise can be interpreted to show an awareness of data indicating that Vioxx might be prothrombotic. She appears to weigh the risk of giving trial participants aspirin (known to be cardioprotective but also to have negative GI effects), considering that it could result in a two-to-four fold increase in negative GI incidents. In that same email, she later writes that perhaps the trial should exclude "high-risk CV patients . . . This may decrease the CV event rate so that a difference between the two groups would not be evident." (Id., ¶ 108.) The February 1997 email

[6] The Court has quoted these emails with alterations and emphasis as they appear in the Complaint.

exchange can reasonably be construed as indicating that Reicin recognizes that Merck faces a dilemma between, on the one hand, giving cardioprotective aspirin to the Vioxx group in the trial, which would likely diminish the appearance of Vioxx's GI superiority and thus undermine the promotional advantage of the trial and, on the other hand, not administering aspirin and possibly exposing Vioxx's tendency to increase the risk of a negative CV event.

The Complaint, in short, sets forth that in spite of possessing data giving it "great concern" of a potential link between Vioxx and adverse CV events, Merck made public statements in the pre-VIGOR period that the drug had a "exceptional" safety profile and that its side effects were mainly "upper respiratory infection, diarrhea and nausea." (Id., ¶¶ 223, 237, 240.) It is substantially likely that, presented with such positive information about a key Merck product, touted as responsible for the company's sales and revenue growth, a reasonable investor in Merck would find that disclosure of the withheld data would have altered the total mix of information available. Following Matrixx, the Court concludes that Plaintiffs have adequately alleged that, by failing to disclose the concern indicated by the results of Protocol 023 and the information contained in the February 1998 Analysis, Merck made misleading statements of material fact about Vioxx between May 21, 1999 (the date of the first press release announcing FDA approval) and March 27, 2000 (the date the VIGOR results were announced).

Merck also argues that statements made prior to March 27, 2000, when the naproxen hypothesis was first presented to the public, are not actionable because pursuit of such claims is logically inconsistent with Plaintiffs' position that their theory of fraud is that Merck made false statements of opinion when it expressed its belief in the naproxen hypothesis. This argument is

unavailing. It is clearly based on the premise that the predicate of Plaintiffs' securities fraud claim must be limited to Merck's allegedly false statements of opinion concerning the naproxen hypothesis. The Court has rejected such a narrow reading of the securities fraud claim.

2. Post-VIGOR Statements

To reiterate, Plaintiffs identify the following types of allegedly fraudulent statements made by Merck following VIGOR: (i) Merck asserted that the naproxen hypothesis was the "likely" explanation for the VIGOR results; (ii) Merck stated it had "no evidence" and "no indication" that Vioxx increased the risk of heart attacks; and (iii) Merck continued to reassure investors that Vioxx had an "excellent" overall safety profile and specifically a "favorable cardiovascular safety profile."[7] Putting aside, for the moment, the statements about Vioxx's safety profile and Merck's professed lack of data indicating the drug's prothrombotic tendency, the Court focuses on the main dispute between the parties – whether Merck's representations about the naproxen hypothesis may constitute an actionable securities fraud violation.

As discussed above, Plaintiffs had argued on appeal that, in evaluating the sufficiency of an earlier version of the Complaint, this Court misinterpreted the nature of the fraud claim. They clarified that the alleged misrepresentation concerning the naproxen hypothesis did not consist of Merck's misleading presentation of an unproven explanation as established fact. Rather, Plaintiffs indicated that the gravamen of the claim is that Merck had falsely represented its belief

[7] Again, as noted above, the Complaint identifies many other statements made in the post-VIGOR period as actionable. These other statements, which generally report Vioxx sales, forecast future performance and express confidence in commercial growth, have not been analyzed in Merck's motion and therefore are not addressed by the Court in this Opinion. As the Court has observed, however, basing a Rule 10b-5 claim on such statements is highly problematic.

in the cardioprotective qualities of naproxen and thus, as a corollary, its belief that the VIGOR results were not indicative of any prothrombotic qualities in Vioxx – in short, its belief in the naproxen hypothesis. The Complaint is indeed quite clear on the nature of the alleged misrepresentation. According to the Complaint, Merck's statements

> attribut[ing] the difference in thromboembolic events in VIGOR to naproxen's purported cardioprotective characteristics (the "naproxen hypothesis"), were materially false and misleading because (a) they constituted an affirmatively false representation that Merck and the Officer Defendants believed in good faith that it was the naproxen hypothesis (rather than VIOXX's prothrombotic effects) that was the most likely explanation of VIGOR's adverse CV results; and (b) failed to disclose that Merck and the Officer Defendants actually believed that use of VIOXX caused serious adverse CV events, and that it was the "mechanism based" effect of VIOXX in suppressing prostacyclin (without suppressing thromboxane) – rather than the "naproxen hypothesis" - that explained VIGOR's results . . . As a result, investors were affirmatively misled as to, and remained unaware of, Merck's and the Officer Defendants' actual beliefs concerning VIOXX's prothrombotic effects, and were materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

(Compl., ¶ 245.)

The Supreme Court has held that statements of belief or opinion may run afoul of the Exchange Act. Va. Bankshares, Inc. v. Sandberg, 501 U.S. 1083, 1087 (1991); Shapiro, 964 F.2d at 282. To meet the element of "misrepresentation of material fact," such a statement must both be a "misstatement of the psychological fact of the speaker's belief in what he says" and "mislead about the stated subject matter." Va. Bankshares, 501 U.S. at 1095. In other words, a viable securities fraud claim based on opinion statements must allege both that the defendant disbelieved the opinion and that the stated subject matter itself constituted a material

misrepresentation. Id. at 1096; In re Donald J. Trump Casino Sec. Litig., 7 F.3d 357, 368-69 (3d Cir. 1993) (holding that securities fraud claim based on defendant's statement of belief could not survive motion to dismiss because complaint did not sufficiently allege that the defendant made a material misrepresentation); accord Eisenberg v. Gagnon, 766 F.2d 770, 776 (3d Cir. 1985) (holding that an opinion may be actionable under securities fraud laws if it lacks a factual basis).

Merck argues that its opinion statements are not actionable because they did not represent that the cardioprotective quality of naproxen was established by scientific proof and because the opinion that the naproxen hypothesis best explained the VIGOR results was based on facts which reasonably justified that opinion. It maintains that Plaintiffs' own factual allegations show that the naproxen hypothesis was a plausible and debatable interpretation of the VIGOR data. According to Merck, this case is similar to Oran, in which the Third Circuit concluded, on a Rule 12(b)(6) motion, that the defendant drug manufacturer's characterization of certain public data, which suggested a link between the drug and a heart valve disorder, did not constitute a material misrepresentation. Oran, 226 F.3d at 283. The Oran plaintiffs argued that the defendant had deceptively downplayed the significance of the data by stating it was "inconclusive" and by stating that further investigation was needed to confirm the suspected link. Id. The Third Circuit, however, agreed with the district court's assessment that those statements could not give rise to a securities fraud claim because they did not contain inaccurate information. Id. Merck argues that its statements that the VIGOR results were likely the result of naproxen's cardioprotectiveness are analogous to the Oran statements in that (1) Merck repeatedly made public statements that further investigation was needed to confirm the naproxen hypothesis and

(2) members of the scientific community, including scientists on the FDA's Arthritis Advisory Committee, expressed a belief in the plausibility of the naproxen hypothesis.

This Court is not persuaded that the factual allegations considered in Oran are analogous to those in this Complaint. Unlike Oran, Merck did not merely downplay the VIGOR results as "inconclusive" of the Vioxx-heart attack connection. Instead, it made statements that, if the factual allegations of the Complaint are to be credited for purposes of this motion, it had no reasonable basis for making. As the Third Circuit noted previously in this matter, a plaintiff may state a § 10(b) claim if it shows that a statement of opinion was issued without reasonable basis. Merck, 543 F.3d at 166 (citing Hershkowitz v. Nutri/System, Inc., 857 F.2d 179, 185 (3d Cir. 1988)). In spite of Merck's arguments that the cardioprotectiveness of naproxen was the subject of active and ongoing debate in the scientific community, the Complaint sets forth an extensive number of detailed facts indicating not only that Merck disbelieved the hypothesis, but also that it was aware of many facts undermining its explanation of the "likely" reason for the VIGOR results. Apart from the pre-VIGOR non-public data, such as the February 1998 Analysis, the Complaint identifies additional information indicating Merck's awareness that the VIGOR outcomes on CV events were not due to a purported cardioprotective effect of naproxen. Some of these alleged facts are:

- after Merck's chief scientist, Defendant Scolnick, received preliminary results of the VIGOR trial, he emailed the following comments to others at Merck, including Defendant Reicin:

> I just received and went through the data . . . The CV events are clearly there . . . It is a shame but it is a low incidence and it is mechanism based as we worried it was. Oates and Alan and Barry were right about the metabolite meanings ie urine Pg [prostaglandin] data.[8]

(Compl., ¶ 138.)

- Scolnick's comments were "an admission that he believed that VIOXX was prothrombotic, and that the reason it was prothrombotic was because it inhibited prostacyclin without inhibiting thromboxane." (Id.)
- Following the internal distribution of the VIGOR results, senior Merck scientists searched for support for the theory that naproxen was cardioprotective, but were able to find only one 1993 article from the European Heart Journal reporting that in a small-scale, 464-patient study, heart attack patients given traditional NSAID flurbiprofen - not naproxen - had lower risks of suffering a second heart attack than those who had taken a placebo. (Id., ¶¶ 141-42.)
- Dr. Fitzgerald, the consultant who had conducted Protocol 023, sent Dr. Nies, the Merck scientist in charge of developing Vioxx, data he characterized as the "best" comparative clinical data on the effect of aspirin and non-aspirin NSAIDs in preventing heart attacks. In that email, dated March 24, 2000, Dr. Fitzgerald concluded that the non-aspirin NSAIDS, including naproxen, "had no significant effect" on the risk of suffering a heart

[8] It appears to the Court that, reading this allegation in the context of the entire Complaint, the email's reference to the urine metabolites regards the observed imbalance between prostacyclin and thromboxane metabolites in the urine of VIOXX patients participating in Protocol 023.

attack. This email was forwarded by Dr. Nies to Dr. Reicin and another senior scientist at Merck. (Id., ¶¶ 143-44.)

- Results from other trials which post-dated VIGOR, specifically another GI study known as ADVANTAGE and two large studies involving Alzheimer's patients, showed statistically significant increases in CV events suffered by Vioxx users. (Id., ¶¶ 162-67; 171, 178-80.)
- Merck manipulated the ADVANTAGE trial data it obtained in April 2000 to list certain deaths as "unknown cause" so that the results did not show a statistically significant difference in heart attack rates between Vioxx and non-Vioxx patients. (Id., ¶ 167.)
- Merck manipulated the data it obtained in April 2001 from the Alzheimer trials so as to report that Vioxx users had a non-statistically significant increase in risk of death. (Id., ¶ 178-83.)

These alleged facts, when taken as true and considered as a whole, plausibly suggest that Merck had no reasonable basis for its public characterization of the VIGOR results as "likely" due to naproxen's cardioprotective quality. It may be that, in light of what Merck argues was the ongoing scientific debate about the cardioprotectiveness of naproxen, Plaintiffs will be unable to prove at trial that the professed belief in the naproxen hypothesis contains an objectively misleading statement, as required by Virginia Bankshares. The Court, however, is tasked on this motion with evaluating whether the factual allegations of the Complaint plausibly establish that the naproxen hypothesis statements constitute actionable misrepresentations for purposes of Plaintiffs' securities fraud claim. It finds that they do.

Defendant Scolnick's additional argument that the naproxen hypothesis statements are immaterial is unavailing. It is clear from the Complaint that Vioxx's commercial success was critical to Merck and that its commercial viability rested on its favorable safety profile as compared to other NSAIDs. (Compl., ¶¶ 77, 106.) Assuming the alleged facts to be true, representations about the likely cause of the four-fold increase in CV events observed in the VIGOR trial's Vioxx patients would, thus, significantly alter the total mix of information about Vioxx. Basic, 485 U.S. at 231-32. The pleading satisfies Basic's materiality standard.

As for Merck's continuing representations about Vioxx's safety profile and its assertions concerning the lack of internal data indicating a prothrombotic effect of Vioxx, the Complaint sufficiently pleads such misrepresentations with particularity under the PSLRA. The Court has considered these misrepresentations of fact in the context of the many detailed factual allegations, discussed above, that Merck was in possession of data contradicting these statements. Merck has argued that, even so, any alleged misstatements about the safety profile of Vioxx are immaterial because the market knew, by the spring of 2000, that Vioxx potentially increased cardiovascular risk. In other words, it argues that the alleged misrepresentations did not significantly alter the total mix of information available to investors. There is no dispute, and the Complaint itself alleges, that Merck stock traded in an efficient market throughout the Class Period. (Compl., ¶ 424.) Merck argues that the stock price promptly incorporated the many items of publicly available information, including statements by senior Merck scientists, that the VIGOR results could be attributed to a cardioprotective quality of naproxen **or** to a prothrombotic quality of Vioxx. According to Merck, the market was repeatedly informed about

Vioxx's potential for increased cardiovascular risk, thus rendering any alleged misrepresentations about its safety profile immaterial. Underscoring the lack of materiality, Merck points to the lack of stock price movement at various points over the years 2002 to 2004 when information regarding the "Vioxx risk hypothesis" was publicized. It is true that the Third Circuit has consistently held that in an efficient market, a lack of stock price movement following disclosure of certain information reveals that the information was immaterial as a matter of law. Merck, 543 F3d. at 167. The possibility of two competing explanations for the VIGOR results, one of which was Vioxx's tendency to increase heart attack risk, is not, however, the crux of Plaintiffs' misrepresentation claim. The claim that Merck made misleading statements about Vioxx's safety profile revolves, rather, around Merck's reassuring investors that it believed that the naproxen hypothesis was the better and more likely explanation.

The issue of materiality necessarily hinges on the market's evaluation of probabilities – in this case the likelihood, or probability, that Vioxx would prove to be prothrombotic and thus ultimately unsuccessful as a product. What Merck's argument ignores is the fact that, although the market knew that there was a chance that Vioxx would prove to be prothrombotic, Merck's representations of opinion consistently sought to reassure the market that the risk was minimal. Thus, in an efficient market, Merck's opinion statements would lead investors to make decisions based upon that perceived reduced risk. For this reason, the Court finds Merck's argument that the safety profile statements are immaterial as a matter of law unpersuasive. Given the nature of the fraud alleged, it is not surprising that the stock price was not affected when the Vioxx-risk theory was discussed, as such information did not disclose either that Merck did not actually

believe in the naproxen hypothesis or that the hypothesis lacked scientific support as the likely explanation.

3. Statements Regarding Withdrawal of Vioxx

Finally, the third group of statements revolves around the withdrawal of Vioxx from the market on September 30, 2004. Gilmartin's statements on that day that the adverse CV data precipitating the withdrawal were "totally unexpected" and that Vioxx could have continued to be sold with an appropriate label cannot, as a matter of law, constitute a material misrepresentation. Even assuming the falsity of the statements, the facts fail to support a substantial likelihood that, had Gilmartin declared instead that Merck suspected all along that Vioxx was prothrombotic based on earlier-known adverse data, or that Vioxx was no longer commercially viable in any form, the total mix of information available to investors on September 30, 2004 would have been altered. On that day, the market was simultaneously incorporating Merck's announcement of the immediate worldwide withdrawal of the company's blockbuster product - its second-best selling during the class period - a decision Merck stated was based on negative safety data about Vioxx. Plaintiffs contend that Gilmartin's statement perpetuated Merck's continuing scheme of misleading investors into believing that Merck held an informed view rejecting the hypothesis that Vioxx was prothrombotic. At that point, however, investors were fully aware that Vioxx was no longer commercially viable due to its association with the increased risk of adverse CV events. Against that development, it is simply not plausible that an investor would consider Gilmartin's statements as having any appreciable impact on the mix of information on which to base investment decisions. Whether or not

Gilmartin's "totally unexpected" statement accurately represented Merck's state of mind bears on a different question than materiality. The market knew on September 30, 2004 that Vioxx had been removed from Merck's portfolio of assets, diminishing the value of Merck securities as an investment, regardless of the veracity of Merck's professed surprise at the adverse CV data coming out of the APPROVe study.

The issue of whether a statement or omitted fact is material is a mixed question of fact and law. TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449-50 (1976). Here, the Court finds that as a matter of law, a common sense reading of the Complaint as a whole indicates that Gilmartin's September 30, 2004 statement does not plausibly meet Basic's materiality standard. To the extent that the § 10(b) claim is based on that statement, it must be dismissed.

In all other regards, however, the § 10(b) claim satisfies the pleading standard under the PSLRA with regard to the material misrepresentation or omission element.

B. Scienter

Scienter, a necessary element of any § 10(b) claim, has been defined as "a mental state embracing intent to deceive, manipulate, or defraud." Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.12 (1976). The exacting pleading standard of the PSLRA requires that plaintiffs plead § 10(b) scienter with particularity. Tellabs, 551 U.S. at 313-14. The PSLRA states that, in all private actions for securities fraud under federal law, "the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). Additionally, the Third Circuit has emphasized that "[t]he PSLRA requires plaintiffs to

specify the role of each defendant, demonstrating each defendant's involvement in the misstatements and omissions." Winer Family Trust v. Queen, 503 F.3d 319, 335-36 (3d Cir. 2007).

To determine whether a plaintiff has sufficiently pled the scienter element of a § 10(b) claim, a court must review the complaint in its entirety. Tellabs, 551 U.S. at 323. "The inquiry . . . is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." Id. at 322-23 (emphasis in original). The Supreme Court has held that determining whether the Complaint pleads the requisite strong inference of scienter requires that the Court "consider plausible nonculpable explanations for the defendant's conduct." Id. at 324. Under Tellabs, "[a] complaint will survive [a Rule 12(b)(6) motion] . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Id.

Merck's brief raises two overarching challenges to the sufficiency of the scienter allegations. Merck argues that Plaintiffs have impermissibly relied on group pleading to assert that Merck and all 22 individual Defendants named in the Complaint possessed the requisite state of mind, without specifying the role of each Defendant in the alleged fraud as required by the PSLRA. Merck further argues that, as to those Defendants about whom Plaintiffs have attempted to make specific allegations, the Complaint fails to establish that those Defendants acted with a culpable state of mind, as articulated by Third Circuit jurisprudence. The Court will address each argument in turn. Scolnick's brief, joining in and reiterating these arguments, raises an

additional point related to the Complaint's inadequacy - that it fails to attribute any misleading statement to him individually. The Court will deal with Scolnick's "attribution" argument in the section below dedicated to him.

1. Group Pleading

The Third Circuit has expressly rejected the group pleading doctrine as inconsistent with the PSLRA's heightened pleading requirement. Winer, 503 F.3d at 337. The group pleading doctrine permits the presumption "that statements in group-published documents including annual reports and press releases are attributable to officers and directors who have day-to-day control or involvement in regular company operations." Id. at 335. In the context of a securities fraud action, the doctrine would "[allow] a plaintiff to plead that defendants made a misstatement or omission of a material fact without pleading particular facts associating the defendants to the alleged fraud." Id. at 335. In Winer, however, the Court of Appeals reasoned that the presumption on which the group pleading doctrine is based runs afoul of the PSLRA's statutory requirement that the involvement of "the defendant" must be set forth with particularity. Id. at 335 (quoting 15 U.S.C. § 78u-4(b)). The court thus concluded that the group pleading doctrine did not survive the enactment of the PSLRA. Id. at 337. Subsequent to the Third Circuit's decision in Winer, a § 10(b) claim cannot survive a motion to dismiss unless it is supported by factual allegations sufficiently demonstrating each defendant's role in the alleged fraud and his or her state of mind in committing such a violation. Id.

The Complaint, as Merck correctly points out, is rife with such patently insufficient "group pleading." It alleges that "Defendants" as a general group engaged in many inappropriate

activities, which taken as a whole, raise a strong inference that they intended to deceive Plaintiffs. Plaintiffs completely side-step Merck's group pleading argument and, moreover, fail to address a critical flaw raised by Merck in its motion – that as to some Defendants, the Complaint does not make any scienter allegations at all. In their opposition brief, Plaintiffs emphasize that various internal emails "graphically demonstrate their actual knowledge of information that contradicted, and rendered false, Defendants' repeated [misrepresentations]." (Opp. Br. at 68.) Plaintiffs' use of the collective pronoun "their" is telling, and reveals a lack of specificity, contrary to the requirements of the PSLRA. The Complaint provides no basis to impute such knowledge to individuals who were not actual participants in those communications. Blanket assertions of Defendants' actual knowledge, or as set forth elsewhere in the Complaint, Defendants' manipulation of clinical trials, or any other group action fall squarely within the bounds of group pleading. Pursuant to the holding of Winer, allegations charging collective involvement or participation and collective state of mind do not suffice to state a claim under the PSLRA.

Though they fail to explain how the securities fraud claim as to many of the Defendants have a factual basis beyond mere group pleading, Plaintiffs do make an argument for the viability of their § 10(b) claim as to certain individual Defendants. These individuals, who together comprise a group referred to as the "Officer Defendants," are Defendants Gilmartin, Scolnick, Reicin, Kim, Lewent, Frazier, Henriques, Anstice and Wold-Olsen. The sufficiency of the scienter pleading as to those individuals will be evaluated below. Insofar, however, as the Complaint relies on broad statements about "Defendants" – whether it be their knowledge,

access to information, involvement in the manipulation of clinical trials, or other circumstances that might give rise to a strong inference of scienter – the Section 10(b) claim fails to meet the pleading requirements of the PSLRA.

2. Officer Defendants

Before proceeding to evaluate the allegations concerning the scienter of the "Officer Defendants," the Court must address the parties' disagreement over what constitutes a culpable state of mind in this case. Generally, scienter may be shown by either conscious misbehavior or recklessness. Suprema, 438 F.3d at 438; see also Tellabs, 551 U.S. at 319 n.3 (noting that "[e]very Court of Appeals that has considered the issue has held that a plaintiff may meet the scienter requirement by showing that the defendant acted intentionally or recklessly."). Recklessness has been defined by the Third Circuit as

> [H]ighly unreasonable (conduct), involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, ... which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.

S.E.C. v. The Infinity Group Co., 212 F.3d 180, 192 (3d Cir. 2000) (quoting McLean v. Alexander, 599 F.2d 1190, 1197 (3d Cir. 1979)). Merck argues that in this case, however, Plaintiffs' Complaint may satisfy the scienter element only by pleading facts that show *knowing* misconduct. Recklessness is not a viable standard, according to Merck, because the nature of the fraud alleged - stating a misleading opinion about the naproxen hypothesis - puts each Defendant's *actual belief* at issue.

Merck's argument is based, in part, on cases dealing with the scienter standard applicable to misrepresentations falling within the PSLRA's safe harbor provision for forward-looking statements. See 15 U.S.C. § 78u-5; see, e.g., Institutional Investors Group v. Avaya, Inc., 564 F.3d 242, 255 (3d Cir. 2009) (discussing breadth and applicability of safe harbor provision); Slayton v. Am. Express Co., 604 F.3d 758, 775 & n. 9 (2d Cir. 2010) (applying actual knowledge standard of scienter in a case involving forward-looking statements and noting that, in a case governed by the PSLRA's safe harbor provision, "plaintiffs must show more than recklessness-an objective inquiry-they must show actual subjective knowledge."). Under that provision, a forward-looking statement may not give rise to securities fraud liability unless the plaintiff demonstrates that the person making the statement had "actual knowledge . . . that the statement was false or misleading." 15 U.S.C. § 78u-5(c)(1)(B). The provision defines "forward-looking" statement, identifying certain categories of statements which generally concern financial projections, management objectives or forecasts of economic performance. 15 U.S.C. § 78u-5(i)(1); see also Avaya, 564 F.3d at 255 (summarizing statutory definition). Defendants' alleged statement of belief in the naproxen hypothesis is not, however, a forward-looking statement. If anything, when the statement was made by Merck, it purported to be a representation of present fact - what Defendants believed at the time was the likely explanation for the VIGOR results. The cases dealing with the scienter standard imposed by the safe harbor provision lend no support to Merck's position that only the stricter "knowing falsity" standard will suffice in this case.

Merck has also argued that Plaintiffs themselves have cast the applicable standard as intentional rather than merely reckless deception by impugning Defendants' actual beliefs in their allegations. It highlights that, in their own words, Plaintiffs have alleged throughout the Complaint that the fraud consists of Defendants' promotion of Vioxx as safe and/or their repeated assertions of the naproxen hypothesis when they "*actually believed* that use of VIOXX caused serious adverse CV events." (See, e.g., Compl. ¶¶ 241, 250 (emphasis added).) This argument fails to persuade the Court.

The Court notes, as the preceding sections of this Opinion have discussed at length, that the wrongdoing on which the securities fraud claim is based is not limited to Merck's allegedly false statements expressing belief in the naproxen hypothesis. Plaintiffs have also challenged as unlawful, among others, Merck's statements that Vioxx had an "excellent" safety profile and its representations that its internal data contained "no indication" of a prothrombotic effect of Vioxx. Defendants have articulated no reason why one theory of the securities fraud claim - that Merck misled investors as to its opinion concerning the naproxen hypothesis - should dictate the state of mind standard for all fraudulent statements and omissions alleged in the Complaint.

More fundamentally, however, the flaw with Defendants' attempt to remove the concept of recklessness from the scienter analysis disregards well-established precedent governing the manner in which scienter may be established. As to any of the asserted bases for Defendants' § 10(b) violation, whether they be opinion-based or not, the Court's role on a motion to dismiss is to examine whether the factual allegations give rise to a "strong inference" of scienter. The law is clear that the "inference that defendant acted with scienter need not be irrefutable, i.e., of the

'smoking-gun' genre." Tellabs, 551 U.S. at 324. Because the standard permits a showing of scienter through evidence circumstantially indicating that a defendant intended to deceive investors, factual allegations that are sufficient to permit a strong inference that a defendant acted with a reckless state of mind may also suffice at the pleading stage to set forth through circumstantial evidence a "strong inference" that a defendant knowingly made misrepresentations of fact and/or opinion. In other words, the incorporation of Defendants' alleged "actual beliefs" into the wrongdoing does not in turn upset the Tellabs holding that a sufficient inference of scienter may be satisfied without direct evidence of a defendant's intent to deceive. Indeed, it is a basic legal proposition that intent is generally demonstrated by means of circumstantial proofs since there is rarely direct evidence of a party's state of mind. See, e.g., Third Circuit Model Criminal Jury Instructions § 5.01 (2009) (providing instruction to jurors that whether a criminal defendant acted with requisite state of mind, whether it be intent, knowledge, willfulness or recklessness, "can be proved indirectly from the surrounding circumstances" in recognition that it is often the case that "the state of mind . . . with which a person acts at any given time cannot be proved directly, because one cannot read another person's mind and tell what he or she is thinking."). Yet, by arguing that nothing short of allegations that Defendants "knowingly" misrepresented their belief in the naproxen hypothesis will sufficiently plead scienter, Merck is essentially arguing that circumstantial allegations giving rise to a strong inference that Defendants did not actually believe in the naproxen hypothesis will not do. The Court finds this approach contrary to Tellabs.

In any event, the debate Merck seeks to introduce regarding a sufficient demonstration of scienter is largely academic at this stage of the litigation. As set forth below, the Court concludes that the allegations of the Complaint are sufficient to demonstrate that Defendants Merck, Scolnick and Reicin acted with the requisite state of mind, whether one applies the reckless or knowing standard. As to the other Defendants, the Court concludes that the allegations are patently insufficient.

a. Scolnick

The Complaint's factual allegations create a strong inference of Defendant Scolnick's culpable state of mind. Scolnick served as Merck's Executive Vice President for Science and Technology and President of Merck Research Laboratories from the beginning of the Class Period through December 31, 2002. Plaintiffs do not, however, rely on his title and oversight responsibilities regarding the development of Vioxx to establish a strong inference that he intended to misrepresent facts regarding Vioxx's safety and/or Merck's belief in the naproxen hypothesis. Scolnick's March 9, 2000 comments regarding the VIGOR results alone suffice to establish that he knew of the possibility that Vioxx was prothrombotic and thus knowingly or recklessly made a false statement when he attributed the VIGOR data to the purported cardioprotectiveness of Vioxx. In his email of that date he states that the VIGOR data show that "the CV events are clearly there . . . and it is mechanism based as we worried it was." (Compl., ¶ 138). These remarks clearly relate back to internal communications, in which Scolnick was also involved, regarding the serious concern about Vioxx's causal relationship to an observed imbalance in prostacyclin and thromboxane metabolites, indicating a tendency of the drug to

cause clotting. Scolnick's March 9, 2000 email also concedes that outside expert Dr. Oates and various senior scientists at Merck "were right about the metabolite meanings ie urine [prostaglandin] data." (Id.) Indeed, the Complaint quotes one of Scolnick's emails from as early as January 14, 1998, predating FDA approval of Vioxx, in which he acknowledges "the issues . . . about MK 966 [Vioxx] and prostacyclin and thromboxane . . ." (Id., ¶ 114.) According to the Complaint, Scolnick participated in various email communications, either as author or recipient, discussing the concern that Vioxx was or at the very least could be prothrombotic. Before Merck announced the VIGOR results to the public, Reicin reported to Scolnick that in spite of her search, she was unable to find any study regarding the cardioprotectiveness of naproxen and had found only one study suggesting the cardioprotectiveness of another traditional NSAID. Later, in April 2000, when the results of the ADVANTAGE study became available internally and showed a statistically significant increase in heart attacks for Vioxx users versus naproxen users, Scolnick criticized the study as serving "no scientific purpose" and "extremely dangerous." (Id., ¶ 166.)

Tellabs requires that the Court "consider plausible non-culpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." Tellabs, 551 U.S. at 324. Scolnick maintains that contrary to Plaintiffs' position, the inference that he stated his true support of the naproxen hypothesis is a more cogent and compelling inference to be drawn from the allegations in the Complaint than the inference that he made statements about Vioxx with the intent to mislead investors. He argues that the emails in which he discusses Vioxx's CV issues have been taken out of context. According to Scolnick, when read together with allegations

concerning Merck's disclosure of all CV data to the FDA and Scolnick's own public acknowledgment (in the October 9, 2001 *New York Times* article) of the two possible explanations for the VIGOR data, the emails indicate that he was engaged in a legitimate analysis of scientific data and that this analysis led him to the honestly-held conclusion that naproxen's cardioprotectiveness was responsible for the VIGOR results. His argument, however, is simply not consistent with facts pled in the Complaint alleging Scolnick's acknowledgment of the "mechanism-based" increase in CV events for patients taking Vioxx and his awareness of the tenuous nature of the naproxen hypothesis. In short, the non-culpable explanations raised by Scolnick in his motion are neither more plausible nor more compelling than the inference that he intentionally misrepresented Vioxx's CV safety profile and his belief in the naproxen hypothesis. As such, the Court concludes that the Complaint adequately pleads scienter with regard to Scolnick's misstatements and omissions of material fact.

Scolnick's motion to dismiss also draws attention to the PSLRA's requirement that an individual defendant's involvement with the alleged fraud be pled with particularity. First, he argues that no claim can lie against him for any statement he did not make, that is, statements contained in press releases, SEC filings and other documents that Scolnick did not sign or prepare and statements made by Merck on or after January 1, 2003, after Scolnick retired from the company. This point is backed by the solid authority of the PSLRA and the Third Circuit's holding in Winer, as discussed above, rejecting the group pleading doctrine in § 10(b) cases.

Next, he focuses on the seven public statements that the Complaint attributes to him, attacking the sufficiency of each for various reasons. The seven statements consist of comments

made by Scolnick himself and statements contained in SEC filings or company reports signed by him. To identify the statements, they appeared in: (1) the 2000 Annual Report; (2) the October 9, 2001 *New York Times* article; (3) a December 11, 2001 *Bloomberg News* article; (4) Merck's April 11, 2002 press release; (5) Merck's 1999 Form 10-K; (6) Merck's 2001 Form 10-K; and (7) the 2002 Registration Statement. Scolnick's arguments as to these statements can be placed into two categories: one dealing with the content of the statements and the other dealing with the issue of attribution.

As for contents, several of the Scolnick statements alleged by the Complaint do not contain actionable misrepresentations. One of the statements, made in Merck's 2000 Annual Report, makes no express or even suggestive remark concerning Vioxx, much less a remark dealing with the misrepresentations alleged in this case. Scolnick is also correct that, under governing Third Circuit jurisprudence, statements that merely recite statistics concerning Merck's financial performance and/or facts regarding Vioxx's then-present market performance do not constitute material misrepresentations. See Advanta, 180 F.3d at 538-39. In Advanta, the Third Circuit held that "factual recitations of past earnings, so long as they are accurate, do not create liability under Section 10(b)." Id. at 538. Nor, the court held, could recitations of previous successes constitute actionable misrepresentations. Id. The Advanta court reasoned that even if such statements were arguably misleading in the sense that the *present* financial condition of the company was not as sanguine as it was in the past, the statements would not alter the total mix of information available to investors. Id. Thus, two other statements attributed to Scolnick, fail to support a Rule 10b-5 claim against him. Those statements appear in Merck's

2001 Form 10-K and 2002 Registration Statement. The 2001 Form 10-K makes statements about Vioxx's successful sales performance in 2001 (asserting, for example, that "Vioxx, Merck's largest-selling product, continued its strong growth in 2001 and was the product leader within the COX-2 class for new prescription volume growth in the United States"), about its approval for certain indications and about its availability in markets worldwide. (Compl., ¶ 316.) The 2002 Registration Statement similarly asserts past sales figures pertaining to "Merck's 'anti-inflammatory/analgesics' product category" and identifies Vioxx as the "largest-selling" product in that category. (Id., ¶ 462.) Such statements merely report past successes. They convey no inaccurate or misleading information about Vioxx's commercial strength based on its safety profile. Pursuant to Advanta, Plaintiffs fail to state a Rule 10b-5 claim to the extent they base that claim upon these statements.

The remainder of the statements identified by Scolnick as attributed to him in the Complaint do contain representations about the safety of Vioxx and/or the naproxen hypothesis. They can plausibly be interpreted by a reasonable investor as expressing Scolnick's endorsement of Vioxx as a safe product and/or his belief in the naproxen hypothesis. The Court has already evaluated whether such statements may constitute actionable misrepresentations or omissions of material fact and held that they properly support a § 10(b) claim.

Turning to the attribution argument, the Court has been presented with the argument that even as to those statements attributed to Scolnick, he cannot be liable for them because the Complaint does not allege that he had "ultimate authority over the statement." Janus Cap. Group, Inc. v. First Derivative Traders, 131 S.Ct. 2296, 2302 (June 13, 2011). Scolnick relies

heavily on the Supreme Court's recent decision in Janus Capital Group Inc. v. First Derivative Traders, in which the Court interpreted what it means to "make" a statement such that a person or entity might be exposed to liability under Exchange Act § 10(b) and SEC Rule 10b-5. Id. at 2301-02. It held:

> For purposes of Rule 10b-5, the maker of a statement is the person or entity with ultimate authority over the statement, including its content and whether and how to communicate it. Without control, a person or entity can merely suggest what to say, not "make" a statement in its own right. One who prepares or publishes a statement on behalf of another is not its maker. And in the ordinary case, attribution within a statement or implicit from surrounding circumstances is strong evidence that a statement was made by - and only by - the party to whom it is attributed.

Id. at 2302. According to Scolnick, Janus makes clear that while attribution is necessary, by itself it is not enough to give rise to a Rule 10b-5 claim against a person or entity.

Scolnick, however, takes the Janus holding out of context. There, the Court addressed a situation in which one legal entity, Janus Capital Management, served as investment adviser and administrator for another entity, Janus Investment Fund, owned entirely by mutual fund investors. The plaintiff had alleged that the investment adviser Janus Capital Management had been significantly involved in preparing misleading statements contained in prospectuses filed with the SEC by mutual fund Janus Investment Fund. Id. at 2305. On this basis, the plaintiff maintained that Janus Capital Management "made" the statements for purposes of Rule 10b-5. Id. The Supreme Court rejected this expansive interpretation of Rule 10b-5 as being at odds with its reasoning that Rule 10b-5 does not support a private right of action against aiders and abettors, as the Court had held in Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A., 511 U.S. 164 (1994).

Scolnick's role in the statements attributed to him is in no way analogous to Janus Capital Management's relationship to the statements issued by Janus Investment Fund. Scolnick was at the time of each attributed statement an officer of Merck. He signed SEC forms and was quoted in articles and reports in his capacity as Merck's Executive Vice President for Science and Technology and President of Merck Research Laboratories. He made the statements pursuant to his responsibility and authority to act as an agent of Merck, not as in Janus, on behalf of some separate and independent entity. Janus does not alter the well-established rule that "a corporation can act only through its employees and agents." Suez Equity Investors, L.P. v. Toronto-Dominion Bank, 250 F.3d 87, 101 (2d Cir. 2001). It certainly cannot be read to restrict liability for Rule 10b-5 claims against corporate officers to instances in which a plaintiff can plead, and ultimately prove, that those officers - as opposed to the corporation itself - had "ultimate authority" over the statement. Yet, this is the premise that underlies Scolnick's argument that he may not be liable for statements actually attributed to him. Taken to its logical conclusion, Scolnick's position would absolve corporate officers of primary liability for all Rule 10b-5 claims, because ultimately, the statements are within the control of the corporation which employs them.

The Court will therefore permit the § 10(b) claim to proceed against Scolnick insofar as it is predicated on misrepresentations about the naproxen hypothesis and/or Vioxx's CV safety profile that were made by and attributed to him.

b. Kim

Kim succeeded Scolnick as the President of Merck Research Laboratories on January 1, 2003, holding that position through the remainder of the Class Period. The Complaint quotes two statements made by Kim, one published in November 2003 and the other on August 26, 2004, defending the safety profile of Vioxx in response to two studies which produced evidence of a Vioxx-heart attack connection. Both statements asserted that, based on data available to Merck from clinical trials, "Merck stands behind" the safety of Vioxx, including specifically its cardiovascular safety. (Compl., ¶¶ 358, 374.) As to Kim's state of mind, however, Plaintiffs rely exclusively on the responsibilities attendant to his position and his access to all of the same information available to his predecessor Scolnick. This factual predicate for his allegedly culpable state of mind is tantamount to an assertion that Kim "must have known" or "should have known" about the data indicating Vioxx's prothrombotic effect. Such assertions, without more specific facts about Kim's actual review or knowledge of the adverse data, fail to plead his scienter with the particularity required by the PSLRA. GSC Partners CDO Fund v. Washington, 368 F.3d 228, 239 (3d Cir. 2004); In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1422 (3d Cir.1997); see also Advanta, 180 F.3d at 539 (finding scienter allegations inadequate because "[a]llegations that a securities-fraud defendant, because of his position within the company, 'must have known' a statement was false or misleading are 'precisely the types of inferences which [courts], on numerous occasions, have determined to be inadequate to withstand . . . scrutiny.'") (quoting Maldonado v. Dominguez, 137 F.3d 1, 10 (1st Cir.1998)).

Plaintiffs also attempt to plead scienter based on Kim's motive and opportunity to commit fraud, once recognized by the Third Circuit as an alternative method to establishing scienter in a securities fraud action. Avaya, 564 F.3d at 276; Burlington Coat Factory, 114 F.3d at 1422. That attempt also fails. In Avaya, the Third Circuit held that, following the enactment of the PSLRA and the Supreme Court's decision in Tellabs, motive and opportunity alone could no longer suffice to establish scienter. Avaya, 564 F.3d at 276. While these considerations might be relevant to state of mind, the scienter inquiry must focus on the totality of the factual allegations to determine if, collectively, they give rise to a strong inference that a defendant intentionally or recklessly deceived investors. Id. at 276-77. Aside from their inability to independently satisfy scienter, the allegations relating to Kim's motive and opportunity to commit fraud do not bolster a scienter inference because they provide no information about how Kim would allegedly benefit in a personal and concrete manner from the fraud. Id. at 278-29; GSC Partners, 368 F.3d at 237-38. Avaya stresses the insufficiency of motives "generally possessed by most corporate directors and officers," such as improving a company's performance, even when that individual's compensation is tied to the success of a transaction or an increase in sales. Avaya, 564 F.3d at 278-79. Yet, the Complaint provides no facts beyond what Avaya has indicated amounts to fairly generic motive and opportunity. It alleges that Kim's motive for making allegedly fraudulent statements about Vioxx's safety stemmed from the link between his bonus and compensation and Merck's sales and earnings.

Considering the motive and opportunity allegations together with other scienter-related allegations, as Tellabs requires, the Court finds the scienter element lacking as to the securities fraud claim against Kim. Accordingly, the claim will be dismissed.

c. Reicin

Reicin was the Executive Director of Clinical Research at Merck Research Laboratories. In that capacity, she reported directly to Scolnick, and her duties included overseeing research regarding the safety and efficacy of Vioxx. Like Scolnick, she was involved in many internal emails discussing Vioxx's CV risks, including Scolnick's March 9, 2000 email stating that the CV events observed in the VIGOR study's Vioxx patients were mechanism-based as they had suspected. The Complaint quotes her February 1997 email expressing her "great concern" that a large-scale study of Vioxx's gastrointestinal outcomes would carry the possibility of increased CV events. This concern was stated in an exchange regarding the proper design for a study that would show that Vioxx was less likely to cause the GI problems associated with other NSAIDs but conceal the CV risks associated with Vioxx's failure to inhibit the COX-1 enzyme. See Section II.A.1, supra (quoting email communication between Reicin and another Merck scientist). Reicin proposed excluding high-risk CV patients from the study so that a difference in CV event rate would not be evident. The Complaint also alleges that it was Reicin who led the effort to find an alternative explanation for the VIGOR results to counter the interpretation that the results demonstrated that Vioxx caused heart attacks. It was she who ultimately reported back to Scolnick regarding "the only study I could find which assessed the potential cardioprotective effects of an NSAID," referring to the study concerning the administration of

flurbiprofen (not naproxen) to heart attack patients. (Compl., ¶ 141.) Weeks later, on March 24, 2000, before Merck issued its press release explaining the VIGOR results, Reicin received an email in which Dr. Fitzgerald, the consultant who had conducted Protocol 023, set forth "the best comparative clin[ical] data on MI [heart attack] and NSAIDs" - data which demonstrated, according to Dr. Fitzgerald, that there was no basis to conclude that NSAIDs other than aspirin were cardioprotective. (Id., ¶¶ 143-44.) The Complaint also alleges that Reicin directed Merck scientists to change the cause of death of certain patients in the ADVANTAGE study so that the disparity in CV events between Vioxx and naproxen users would not appear to be statistically significant.

Based on these allegations, the Court concludes that the Complaint satisfies the strong inference standard of the PSLRA as to Reicin's state of mind.

d. Gilmartin

The scienter allegations against Gilmartin center on his position at Merck. Gilmartin was Merck's Chairman, President and Chief Executive Officer during the Class Period. Plaintiffs allege that he was responsible for keeping informed of data regarding Vioxx and clinical testing of the drug and that Scolnick, and later Kim, reported to him regularly about such matters. For the reasons discussed above, such "must have known" allegations rooted in a defendant's role as an officer, director or other management position do not adequately plead scienter in the context of a Section 10(b) securities fraud claim.

The Complaint also alleges that Gilmartin made material misrepresentations by signing various annual and quarterly SEC filings, which were knowingly or recklessly misleading based

on their access to information that contradicted Merck's public statements. These averments do not set forth with the particularity required by the PSLRA that Gilmartin acted with the requisite state of mind in the alleged fraud. Winer, 503 F.3d at 334-35. In Winer, for example, the Third Circuit dismissed the Rule 10b-5 claims against various individual defendants, finding the allegations that they "were responsible for the accuracy of the public reports and releases" and that they had "access to, control over, and ability to edit and withhold dissemination of [the corporation's] press releases and SEC filings" did not adequately plead a claim under Section 10(b). Id. at 334-35; see also Kenilworth Partners, L.P. v. Cendant Corp., 59 F.Supp.2d at 428 (observing that courts have rejected arguments that scienter of corporate officer or director may be based on access to information and/or signing SEC Form 10-K).

The § 10(b) claim against Gilmartin thus fails to surmount Merck's motion to dismiss for failure to plead scienter.

e. Lewent, Frazier, Henriques, Wold-Olsen and Anstice

The securities fraud claims against the other Officer Defendants suffer from the same types of deficiencies as the claim against Gilmartin. Defendant Lewent was Merck's Senior Vice President and Chief Financial Officer during the Class Period. Her involvement in the fraud, according to the Complaint, appears to consist of signing various SEC forms. Plaintiffs point to no factual allegations in the Complaint that would give rise to a strong inference of Lewent's scienter.

Frazier was Merck's General Counsel during the relevant time period. Plaintiffs argue that as General Counsel he was responsible for guiding Merck in is regulatory dealings with the

FDA and must therefore have been privy to the internal Merck data concerning Vioxx. They also argue that, even if he was not aware of Vioxx's cardiovascular risks before 2000, he surely would have become aware of those risks once product liability lawsuits were filed that year and thus would have been obligated to investigate the truth of the allegations against Merck. These allegations of scienter barely rise above speculation, much less meet the strong inference standard of the PSLRA. Moreover, Plaintiffs have not alleged any facts that demonstrate Frazier's personal involvement in the alleged fraud. The group pleading doctrine is not available to Plaintiffs, and thus statements in public reports and filings made by Merck cannot be attributed to Frazier simply because he is a corporate insider with involvement in regular company operations. Winer, 503 F.3d at 335.

These same deficiencies apply to the securities fraud claims against Defendants Henriques, Anstice and Wold-Olsen. Henriques, Merck's Vice President and Controller during the Class Period, and Wold-Olsen, Merck's President of Human Health for Europe, the Middle East and Africa during the Class Period, are not individually associated with the alleged fraud, other than by virtue of their position within Merck. Anstice, identified as President of Merck's Human Health Prescription Division, similarly lacks a connection to the alleged fraud. Although Plaintiffs point to two press releases issued in 1999 and 2000, respectively, in which Anstice is quoted as touting the strong commercial performance of Vioxx, these statements do not regard the safety of the drug or otherwise make statements rendered misleading by the information they omit. In other words, they do not touch upon the subjects of the alleged fraud and do not suffice to plead Anstice's role in the wrongdoing under § 10(b). Further, to the extent Plaintiffs argue

that Anstice's personal role in the fraud consisted of his responsibility to train the sales force and thus supports the inference that he executed the scheme to propagate the naproxen hypothesis, these assertions are made solely in the brief and find no support in the factual allegations of the Complaint. The Complaint's quotation of a memo by Anstice to his staff encouraging the sales force to view Merck as engaged in battle with Pfizer, which marketed competing product Celebrex, is offered as a basis upon which to draw the inference that Anstice was privy to information contradicting the naproxen hypothesis, yet the memorandum states nothing about Vioxx's side effects or safety profile. Moreover, it bears noting that the memorandum was written in February 1998. The Complaint contains many factual allegations that at or about that time various Merck employees were exchanging e-mails about the prostacyclin data and February 1998 Analysis were indeed occurring but none implicate Anstice as involved in those communications.

In short, the securities fraud claims against most of the "Officer Defendants" lack sufficient factual basis to withstand Defendants' motion to dismiss. Apart from the particularized allegations concerning individual Defendants Scolnick and Reicin, the factual allegations about the participation of the other "Officer Defendants" fail to satisfy the heightened pleading requirements of the PSLRA. For the reasons set forth above, the Section 10(b) claims against all individual Defendants other than Scolnick and Reicin will be dismissed without prejudice.[9]

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[9] The analysis of the Complaint before the Court does not, of course, foreclose the possibility that discovery might reveal information as to a particular Defendant whose individual culpability was not sufficiently alleged in the Complaint. See Winer, 503 F.3d at 337 (leaving open the possibility of a motion to amend the pleadings based on scienter-related information

3. Merck

The Complaint sufficiently pleads a strong inference of scienter as to Merck. The scienter of certain individuals employed by the corporation may be attributable to the corporation. The Second Circuit has held that to assert the scienter of a corporate defendant in a securities fraud case, "the pleaded facts must create a strong inference that someone whose intent could be imputed to the corporation acted with the requisite scienter." Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc., 531 F.3d 190, 195 (2d Cir. 2008). Here, the Complaint adequately pleads scienter as to two agents of the corporation, corporate officers Scolnick and Reicin. Merck has not argued, moreover, that the scienter of these individuals could not be imputed to the corporation. Accordingly, the facts of the Complaint sufficiently support a strong inference that Merck made the alleged misrepresentations with the requisite state of mind.

C. Loss Causation

The loss causation element of a §10(b) claim "requires a plaintiff to show that a misrepresentation that affected the integrity of the market price *also* caused a subsequent economic loss." Erica P. John Fund, Inc. v. Halliburton Co., 131 S.Ct. 2179, 2186 (2011) (emphasis in original). It is not enough that a plaintiff may have bought stock at an inflated price in reliance on misrepresentations or omissions; rather, establishing loss for securities fraud requires that the share value have depreciated as a result of the disclosure of information that was misrepresented or concealed. Dura, 544 U.S. at 344. The Third Circuit has held that "to satisfy

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gathered in discovery). Accordingly, the Court's dismissal of the securities fraud claim against certain Defendants will be without prejudice.

the loss causation requirement [on a § 10(b) claim], the plaintiff must show that the revelation of that misrepresentation or omission was a substantial factor in causing a decline in the security's price, thus creating an actual economic loss for the plaintiff." McCabe, 494 F.3d at 425-26. In other words, the loss causation inquiry is concerned with proximate cause. Id. at 426, 428. Such an inquiry can be highly factual, and thus the Third Circuit has noted that it is often unsuited to disposition based on the pleadings alone. Id. at 427 n.4. Loss causation is adequately alleged if it meets Rule 8(a)'s standard by giving a "short and plain statement" of economic loss and its causal connection to the alleged misrepresentations and/or omissions. Dura, 544 U.S. at 346-47.

Applying these principles, the Court must examine whether the Complaint alleges that Plaintiffs sustained economic loss, i.e. a price drop in Merck securities, upon the public release of information revealing the misleading nature of previous misrepresentations or omissions Merck made about Vioxx. Plaintiffs identify a series of corrective disclosures, each of which allegedly made a partial revelation of the fraud and caused a decline in the market value of Merck stock.

1. The Corrective Disclosures

The first set occurred in October 2003 upon the reporting of adverse findings made in a large-scale epidemiological study supported by Brigham and Women's Hospital in Boston, an affiliate of Harvard Medical School. In this study, which the Court will hereinafter refer to as the "Harvard study," a comparison of Vioxx, Celebrex and a placebo indicated that Vioxx use was associated with an increased risk of heart attack. An abstract for the paper regarding the Harvard study to be presented at a meeting of the American College of Rheumatology began to circulate

in September 2003. Although the results of the Harvard study had not yet become publicly available, October 22, 2003 saw the publication of two negative reports: a Reuters article stating that Vioxx sales were "suffering from clinical trial data suggesting it might slightly raise the risk of heart attacks" and a Credit Suisse First Boston analyst report warning that "Upcoming ACR [American College of Rehuematology] Data Would Put Increase Pressure on [Vioxx] Franchise." (Compl., ¶¶ 415, 418). The Complaint alleges that, in response to these first public reports of the Harvard study's findings of an observed prothrombotic effect of Vioxx, the price of Merck stock fell almost 7% on October 22, 2003, to close at $45.72. On October 30, 2003, the stock declined a further 2%, allegedly as a result of a *Wall Street Journal* article published that day reporting the specific findings of the Harvard study.

The second corrective disclosure occurred, according to the Complaint, on the day Merck pulled Vioxx from the market. On September 30, 2004, Merck announced the immediate withdrawal of Vioxx because of "an increased risk of confirmed cardiovascular events" associated with Vioxx use. (Id., ¶ 419). Plaintiffs allege that in response to this corrective disclosure, Merck's stock dropped 27% in value, from a closing price of $45.07 on September 29, 2004 to close at $33 per share on September 30, 2004.

The third corrective disclosure, made on November 1, 2004, consisted of a *Wall Street Journal* article which asserted that Merck had for many years been aware of and actively concealed adverse information concerning Vioxx's CV event risk. The article, according to the Complaint, described internal communications and documents reflecting Merck's concern that Vioxx was associated with an increased risk of heart attack, including the February 1997 email in

which a Merck scientist warns that a large scale GI outcomes trial would "kill the drug" and Scolnick's March 2000 email observing that the VIGOR results showed that greater incidence of CV events in Vioxx users was "mechanism-based as we worried it was." (Id., ¶ 214.) The article also reported, based on the reporter's review of an internal marketing document, that Merck had instructed its salespersons on how to dodge questions from physicians about Vioxx's cardiovascular safety. (Id., ¶ 215.) The Complaint alleges that in response to the revelation of this information concerning Merck's awareness of Vioxx's prothrombotic qualities and active efforts to conceal such information, Merck stock fell 9.7% on heavy trading volume. (Id., ¶ 218.) It further alleges that this drop constituted the greatest one-day percentage decline of the stock since 1990, excluding the precipitous drop of September 30, 2004. (Id.)

2. Loss Causation Based on Partial Corrective Disclosures

The Court, as a threshold matter, notes its agreement with the approach taken by the Hon. Faith S. Hochberg in In re Bradley Pharmaceuticals, recognizing that a loss causation analysis can be predicated on a series of partial corrective disclosures. In re Bradley Pharms., Inc. Sec. Litig., 421 F.Supp.2d 822, 828-29 (D.N.J. 2006). Bradley reasoned that Dura did not impose any rigid form on the nature of a corrective disclosure but rather allowed a pragmatic approach to loss causation. Id. at 828-29. The Bradley court thus concluded, on a Rule 12(b)(6) motion, that the plaintiffs had adequately pled loss causation by alleging multiple disclosures, each of which partially revealed the truth. Id. Likewise, in this case, no single disclosure fully shed light on the nature of the misrepresentation, which included both an objective component (that there was no evidence that Vioxx was not prothrombotic/the VIGOR results were attributable to the

cardioprotectiveness of naproxen) and a subjective component (that Merck believed the naproxen hypothesis). The exposure of the alleged fraud need not occur in a single, all-encompassing corrective disclosure. Such a requirement would be at odds with Dura in that it would essentially "allow wrongdoers to immunize themselves with a protracted series of partial disclosures." Freedland v. World Commc'ns, Ltd., 233 F.R.D. 40, 47 (D.D.C. 2006); see also Alaska Elec. Pension Fund v. Flowerserve Corp., 572 F.3d 221, 230 (5th Cir. 2009) (holding same).

The Court concludes that, under the standard set by Federal Rule of Civil Procedure 8(a) and Dura, loss causation has been adequately pled in the Complaint. Assuming the truth of the factual allegations, two of the three events made revelations regarding the falsity of Merck's misrepresentations about Vioxx, and the Complaint draws a plausible connection between the revelations and loss. However, the Court further holds that, as a matter of law, the third corrective disclosure identified by Plaintiffs, which post-dates the withdrawal of Vioxx from the market, cannot form the basis of loss causation related to the fraud alleged in the Complaint. The Court will discuss each of the alleged corrective disclosures.

a. October 2003 Disclosures

The Complaint plausibly establishes that the October 2003 publication of information regarding the Harvard study was partially curative of the fraud because it indicated that the naproxen hypothesis was false. Though Merck argues that the reports of October 22 were not revelatory because they did not refer to the Harvard study by name, such specificity is not required to plead loss causation. The articles, considered in the context of the other factual allegations, were the first indication that clinical study results - revealed days later in the October

30 *Wall Street Journal* article to be the Harvard study - had provided scientific support for the view that Vioxx increased heart attack risk. Merck makes the argument that a causal connection is lacking because other adverse information announced that day was responsible for the decline in the price of Merck stock on October 22, 2003. This argument is unavailing on a motion to dismiss. All that is required to satisfy Rule 8(a) is that the plaintiff "provide a defendant with some indication of the loss and the causal connection that the plaintiff has in mind." Dura, 544 U.S. at 347. Plaintiffs' Complaint need not rule out the possibility that other market forces, in particular Merck's announcement on October 22, 2003 that it was reducing earnings estimates, caused the almost 7% drop in Merck stock price. Neither Dura nor any other legal authority cited by Merck impose such a pleading requirement on a securities fraud plaintiff. So long as the Complaint plausibly alleges that a revelatory disclosure was a substantial cause of the stock value's decline - and it has - Plaintiffs' pleading burden has been met.

b. September 30, 2004 Disclosure

Merck's September 30, 2004 statement, made in connection with the withdrawal of Vioxx, that the ESMB overseeing the APPROVEe clinical trial recommended that the trial be halted because of "an increased risk of confirmed cardiovascular events" in Vioxx users (Compl., ¶ 204) clearly undermines the naproxen hypothesis. Merck argues, however, that disclosure of the APPROVe data did not alert the market to Merck's "actual beliefs" about Vioxx, which according to the Complaint itself was not revealed until one month later. Thus, Merck maintains, Plaintiffs have failed to plead any plausible connection between the alleged fraud and the September 30, 2004 disclosure. This argument misses the mark because it overlooks the dual

component to Merck's alleged fraud - the misleading statement as to its subjective belief and the misleading statement as to an objective matter. The objective component asserted that the cardioprotectiveness of naproxen was the likely explanation for the increased heart attack risk observed in the VIGOR study's Vioxx patients. The information made public on September 30, 2004 - that Vioxx would be taken off the market immediately due to serious cardiovascular safety concerns - disclosed the critical portion of Merck's alleged fraud regarding the naproxen hypothesis. Indeed, to the extent the fraud consisted of assurances of Vioxx's "excellent" safety profile, the disclosure fully revealed what Plaintiffs allege had been concealed from the market - that Vioxx had prothrombotic qualities. In arguing that the news that Vioxx may not be sold given evidence of its cardiovascular risk does not connect the fraud to the stock price drop, Merck would appear to be stating that nothing short of a contemporaneous admission by Merck that it fabricated the naproxen hypothesis would suffice as a corrective disclosure. Dura and its progeny do not demand, as set forth above, that corrective disclosures be complete, or put differently be the "mirror image" of the alleged fraud. As the Fifth Circuit observed, "[i]f a fact-for-fact disclosure were required to establish loss causation, a defendant could defeat liability by refusing to admit the falsity of its prior misstatements." Alaska Elec. Pension Fund, 572 F.3d at 230.

Indeed, while a fraudulent representation of opinion is actionable, it is only actionable to the extent that the opinion concerns an underlying fact. Va. Bankshares, 501 U.S. at 1096. Thus, it is the disclosure of corrective information concerning the underlying fact and the market's reaction to that disclosure which is critical to establishing the causal connection between the

alleged fraud and the loss for which investors seek to recover. For example, in Lentell v. Merrill Lynch, the securities fraud alleged consisted of a stock analyst's false opinions about whether a particular stock rated as a "buy" or "accumulate;" the plaintiffs based their Rule 10b-5 claim on the allegation that the analyst made "buy" and "accumulate" recommendations to investors even though the analyst did not truly believe those recommendations. Lentell v. Merrill Lynch & Co., Inc., 396 F.3d 161, 165-67 (2d Cir. 2005). The Second Circuit Court of Appeals quite properly held in Lentell that the plaintiffs had failed to allege loss causation because they did not allege a corrective disclosure as to the *subject* of the stock analyst's fraudulent recommendation. Id. at 175. The Lentell court pointed out that there was no "corrective disclosure regarding the falsity of those recommendations." Id. In other words, it held that loss causation was lacking because the complaint did not allege that the market reacted to a revelation of the falsity of facts asserted; indeed, it observed that the allegedly fraudulent statements did not concern any facts at all. Id. at 176. Concomitantly and necessarily, in situations where the fraudulent representation of opinion concerning underlying facts ultimately results in a corrective disclosure that the opinion was false as to the underlying facts, the resulting drop in prices from the inflated value caused by the false opinion clearly constitutes "loss causation."

c. November 1, 2004 Disclosure

Lastly, the Court tackles an unusual premise for loss causation - a corrective disclosure made after it was clear that the product about which misrepresentations were made had lost all of its commercial viability. Plaintiffs identify a November 1, 2004 *Wall Street Journal* article as the final corrective disclosure, alleging that it was not until the publication of that article that

"investors finally learn[ed] that Merck and the Officer Defendants . . . had actually believed all along that Vioxx was prothrombotic." (Compl., ¶ 213.) The Complaint alleges that the 9% stock price decline of that day was the market's reaction to the revelation of the full extent of the fraud. Merck makes various arguments why the November 1, 2004 "corrective disclosure" – assuming the truth of the fraud allegations – cannot form the basis of loss causation, but their core argument is as follows: upon the withdrawal of Vioxx from the market, Merck securities had realized all the loss that could be connected to any allegedly false statement or omission made by Merck bolstering the marketability and profitability of the drug. Put differently, as Merck illustrated at oral argument, the securities fraud revolves around the allegedly artificial value added to Merck securities by misrepresentations or omissions concerning the naproxen hypothesis, and more broadly, the CV safety profile of the drug. Once the asset represented by Vioxx's commercial viability and performance was removed from Merck's portfolio, and that development was promptly incorporated into the stock price by an efficient market, no further price drop could be linked to the artificial inflation created by the market's false perception of Vioxx's commercial viability.

The Court agrees. The factual allegations of the Complaint, properly credited by the Court on a motion to dismiss, render loss causation based on the November 1, 2004 revelation of purportedly curative information impossible. By that date, the market had been disabused of its perception that Vioxx was a viable product despite the known information about its possible CV risks. Prior to September 30, 2004, the market was able to assess the value of Merck securities by weighing the adverse CV information about Vioxx, gleaned from VIGOR, the Harvard Study,

the Kaiser study and other publically available information, against Merck's own evaluation of the risk communicated through its reassuring statements that it stood behind the safety profile of its drug and through statements concerning the naproxen hypothesis. That risk assessment necessarily changed on September 30, 2004, when Merck withdrew Vioxx from the worldwide market specifically due to serious concerns with its prothrombotic risks. According to Plaintiffs' own allegations, Merck artificially inflated the market price for its securities by giving the market a false explanation for the higher rate of adverse CV events in patients taking Vioxx than those taking naproxen, the VIGOR study's comparator drug. The September 30, 2004 disclosure revealed that Merck's naproxen hypothesis explanation and its reassurances about the CV safety of Vioxx were not to be credited. That curative disclosure, assuming it in fact revealed a deception, would have deflated all false valuation of Merck stock predicated upon the market's perception that the company's blockbuster product was a commercially viable product notwithstanding adverse CV data.

The November 1, 2004 disclosure, moreover, does not correlate to the fraud alleged. "[T]he loss causation element requires the plaintiff to prove 'that it was the very facts about which the defendant lied which caused its injuries.'" Berckley Inv. Group, Ltd. v. Colkitt, 455 F.3d 195, 222 (3d Cir. 2006) (quoting Caremark, Inc. v. Coram Healthcare Corp., 113 F.3d 645, 648 (7th Cir. 1997)). According to Plaintiffs, the information published in the November 1, 2004 article corrected a prior misleading statement or omission because it revealed that Merck had long been aware of, and actively concealed, material adverse information concerning Vioxx's CV risks. This information, however, does not shed any light on the falsity of Merck's statements

made to boost Vioxx sales and thus Merck stock price; as discussed, that revelation was complete on September 30, 2004. Instead, as Plaintiffs concede in their opposition brief, the disclosure revealed information about Merck's state of mind in making false representations about Vioxx, that is, that the statements defending its CV safety profile were made intentionally. (Opp. Br. at 109.) Facts related to scienter are not curative of misrepresentations or omissions, particularly where, as here, information revealing the falsity of the statements made had already been disclosed to the market, and Plaintiffs cite no authority to the contrary.

Plaintiffs, at oral argument, maintained that the post-withdrawal information was curative and affected the stock price by exposing the lack of integrity in Merck's management and business practices. This argument, however, takes a somewhat obtuse approach to characterizing the fraud at issue. The core of this action puts representations about the CV risks of Vioxx at issue. The Rule 10b-5 claim is not based on Merck's dissemination of misleading information about the quality of its management. To accept that the integrity of the company can be understood to be inherently at issue in the allegations about the manner in which Merck handled adverse Vioxx data would stretch the Complaint beyond recognition, and, moreover, contravene the well-reasoned jurisprudence regarding loss causation. To establish proximate cause between the fraud and the loss, revelations must, at a minimum, relate to the facts about which a defendant allegedly lied. McCabe, 494 F.3d at 428. Otherwise, a securities fraud claim might inappropriately permit an investor to recover losses unrelated to the wrongdoing. Id. The Third Circuit's observation about the function of the loss causation requirement in a securities fraud claim is particularly applicable: loss causation "limits the circumstances in which an investor can

sue for a failed investment, so that the individual responsible for the misrepresentation or omission does not become an insurer against all the risks associated with that investment." Id. at 425 n.3. The quality of corporate management is, indeed, a risk inherent in every investment, and might very well materialize in a case involving claims that a company has intentionally misled investors. The Court has uncovered no legal authority holding that disclosure of information concerning the probity of management might constitute a component of loss causation where corporate management is not the subject matter of the misrepresentations or omissions.

D. Reliance

In lieu of pleading that they invested in Merck securities in reliance on Defendants' alleged misrepresentations and omissions concerning Vioxx, Plaintiffs assert they are entitled to a presumption of reliance under two alternative theories. Merck argues that neither applies to Plaintiffs' § 10(b) claim and thus the claim must be dismissed for failure to make a *prima facie* demonstration of reliance in the Complaint.

The Complaint invokes the presumption recognized in Affiliated Ute Citizens of Utah v. United States, which applies when the securities fraud claims are based "primarily [on] a failure to disclose." 406 U.S. 128, 153 (1972). Merck's argument for the non-applicability of this theory at the pleadings stage is unavailing. It is based on a characterization of the alleged fraud as limited to the naproxen hypothesis misrepresentation. For the reasons discussed in Section II, supra, this Court has determined that the fraud alleged in the Complaint also consists of statements concerning Vioxx's safety profile and side effects. According to the Complaint, these

statements were rendered misleading by the failure to disclose material information about the possible CV risks associated with Vioxx use. Assuming the facts of the Complaint to be true, the Court discerns no reason to conclude on a Rule 12(b)(6) motion that the presumption of reliance under Affiliated Ute Citizens of Utah is not available to Plaintiffs.

The Complaint also invokes the presumption of reliance to which investors are entitled under the fraud-on-the-market doctrine. In Basic, the Supreme Court recognized that in an efficient market, the market price of a security will reflect all publicly available information, including material misrepresentations. Basic, 485 U.S. at 246. It reasoned that an efficient market's incorporation of information together with an investor's reliance on the integrity of that price justifies the presumption of a causal connection between the misrepresentation and the investor's decision to buy or sell a security. Id. at 246-47. The Supreme Court held that "[b]ecause most publicly available information is reflected in market price, an investor's reliance on any public material misrepresentations, therefore, may be presumed for purposes of a Rule 10b-5 action." Id. at 247. The fraud-on-the-market theory of reliance is not applicable, however, when corrective information has "credibly entered the market and dissipated the effects of the misstatements." Id. at 249.

Merck argues that Plaintiffs cannot invoke the fraud-on-the-market doctrine because the truth about Vioxx's potential for cardiovascular risk was well-known to the market, thus negating the materiality of any alleged misstatement or omission and destroying the presumption that the market price reflected the alleged misrepresentation. This argument amounts to a fact-intensive truth-on-the-market defense by Merck. It maintains that the market price reflected the available

adverse information about Vioxx, thus rebutting the presumption of a causal connection between Merck's alleged misrepresentations about Vioxx's CV risks and/or the naproxen hypothesis and a transaction in Merck securities. Merck's argument misses the mark because the fraud alleged is not focused on Merck's concealment of the possibility of Vioxx's prothrombotic qualities. Rather, the fraud is premised on Merck's representations that in its view, and based on its data, Vioxx was not prothrombotic, Vioxx had a favorable CV safety profile, and the VIGOR results were attributable to the cardioprotectiveness of naproxen. The alleged fraud, at bottom, consists of Merck's repeated reassurances that in spite of apparently negative data about the CV effects of Vioxx, Merck stood behind the safety of the drug and supported the naproxen hypothesis. Not only has Merck not demonstrated that, based on the Complaint itself, the market was aware of curative information, but it has also failed to demonstrate that any such corrective information had been conveyed to the public "with a degree of intensity and credibility sufficient to counter-balance effectively any misleading information created by" the alleged misstatements. In re Apple Computer Sec. Litig., 886 F.2d 1109, 1116 (9th Cir.1989). In short, the factual allegations of the Complaint, assumed to be true, support Plaintiffs' fraud-on-the-market theory of reliance.

III. Control Person Claim Under Section 20(a) of the Exchange Act

Count II of the Complaint asserts a claim against each of the Officer Defendants under Section 20(a) of the Exchange Act, which "creates a cause of action against individuals who exercise control over a 'controlled person,' including a corporation, that has committed a

violation of § 10(b)." Avaya, 564 F.3d at 252; see also 15 U.S.C. §78t(a). A Section 20(a) claim thus imposes secondary liability on the controlling person for the wrong committed by the one who is controlled. Suprema, 438 F.3d at 284-85. Merck and Scolnick both argue that this claim should be dismissed in its entirety for failure by Plaintiffs to state a claim under § 10(b). The wind has been taken out of the sails of this argument, of course, as the preceding discussion concludes that Plaintiffs have adequately stated that Merck, here the "controlled person" within the meaning of Section 20(a), has committed a primary violation of Section 10(b).

A viable control person claim does entail additional elements, as set forth in the Third Circuit's seminal case on control person liability, Rochez Brothers, Inc. v. Rhoades, 527 F.2d 880, 890 (1975), and its progeny. The three elements of a Section 20(a), or "control person" claim are as follows: (1) the defendant controlled another person or entity; (2) the controlled person or entity committed a primary violation of the securities laws; and (3) the defendant was a culpable participant in the fraud. Suprema, 486 F.3d at 286; Rochez Bros., 527 F.2d at 890. Once the plaintiff establishes a prima facie claim under Section 20(a), the burden shifts to defendant to show that he acted in good faith. Pasternak, 561 F.Supp.2d at 502-03 (citing S.E.C. v. First Jersey Sec., Inc., 101 F.3d 1450, 1473 (2d Cir. 1996)).

Merck and the individual Defendants who have moved to dismiss together with Merck have raised no further challenge to the Complaint's control person claim, other than the failure to plead a primary violation of Section 10(b). Thus, the Court will refrain from examining the sufficiency of the claim against those individuals in other respects.

Scolnick, who has filed his own motion to dismiss, does challenge the sufficiency of the

other two elements. His arguments, however, lack merit. First, Scolnick takes the position that the Complaint relies on mere titles and duties to establish that he had control over Merck's public statements. Plaintiffs, however, allege that Scolnick was "one of Merck's chief spokespersons in connection with information provided to the public" about Vioxx. (Compl., ¶ 32.) It further alleges that, in his role as President of Merck's Research Laboratories, he was "intimately involved in and fully conversant with the development, research, and testing" of Vioxx. (Id.) The factual allegations support the inference that Scolnick provided and was able to control the contents of Merck's public statements about the safety of Vioxx. Indeed, according to the Complaint, many of the statements about that subject and about Merck's backing of the naproxen hypothesis were made by Scolnick himself. Second, Scolnick takes the position that the Complaint fails to allege his culpable participation in Merck's fraud. Culpable participation refers to either knowing and substantial participation in the wrongdoing or inaction with the intent to further the fraud or prevent its discovery. Rochez Bros., 527 F.2d at 890; In re Digital Island Sec. Litig., 223 F.Supp.2d 546, 562 (D.Del. 2002). Scolnick's argument is belied by the ample factual allegations concerning his involvement in the development and clinical testing of Vioxx, his awareness of the prothrombotic issue, and his participation in the propagation of the naproxen hypothesis. See Section II.B.2.a, supra (discussing Scolnick's personal role in alleged fraud and his scienter.) Of course, Scolnick does bring up a valid point in that a control person claim cannot lie against him to the extent it is based on false or misleading statements made by Merck after he retired from the company on December 31, 2002. Plainly, Scolnick could not be a controlling person or culpable participant after his retirement. The Court therefore concludes

that the Complaint adequately states a control person claim against Scolnick predicated on Merck's alleged commission of primary violations of Rule 10b-5 on or before December 31, 2002.

For the foregoing reasons, Merck's motion to dismiss the control person claim will be denied. Scolnick's motion to dismiss the control person claim will be granted in part and denied in part.

IV. Insider Trading Claim

Count III of the Complaint asserts an insider trading claim against Defendants Gilmartin, Scolnick, Frazier, Lewent, Anstice, Wold-Olsen, Clark and Kelley (collectively, the "Insider Trading Defendants"). This claim arises under Section 20A of the Exchange Act, which creates a private cause of action for individuals who traded contemporaneously with corporate insiders when the latter were "in possession of material, nonpublic information." 15 U.S.C.A. § 78t–1(a). Insider trading claims are derivative. Advanta, 180 F.3d at 541. To assert a colorable insider trading claim, a plaintiff must allege "a separate underlying violation of the Exchange Act." Id.; see also In re Cendant Corp. Litig., 60 F. Supp. 2d 354, 378 (D.N.J. 1999).

Merck argues that because Plaintiffs have failed to plead an actionable predicate violation of the Exchange Act as to each Insider Trading Defendant, the Complaint necessarily fails to state a Section 20A claim upon which relief may be granted. In large part, Defendants are correct. The Complaint fails to state an independent Exchange Act violation as to all of the Insider Trading Defendants except for Scolnick. Moreover, Section 20A expressly requires that

the insider have traded the stock "while in possession of material, nonpublic information." Yet, as discussed in the Court's analysis of Plaintiffs' deficient § 10(b) claims, Plaintiffs rely heavily on supposition to assert that Defendants knew of Merck's internal adverse CV data concerning Vioxx. The only Insider Trading Defendant against whom non-conclusory allegations of knowledge are pled is Scolnick.

Scolnick has moved separately, but in his motion simply joins in Merck's argument without raising any unique grounds. The argument that the insider trading claim is not viable for lack of a predicate Exchange Act violation is, of course, futile as to Scolnick. The Court, additionally, notes that while the parties have not discussed the other elements of an insider trading claim, they too appear to be sufficiently pled as to Scolnick. See Cendant, 60 F. Supp. 2d at 378 (holding that insider trading claim requires that the corporate insider have traded company securities contemporaneously with the plaintiff). The Complaint alleges that Scolnick made a sale of Merck securities during the Class Period, by exercising stock options on October 25, 2000 and then, on the same day, selling those 381,200 shares of Merck common stock in the open market.

Accordingly, the Court will grant Merck's motion to dismiss the Section 20A claim. Scolnick's motion to dismiss this claim will be denied.

V. Claims under the 1933 Securities Act

A. Sections 11 and 12 Claims

Count Four of the Complaint asserts a claim under Section 11 of the Securities Act, 15 U.S.C. § 77k, and Count Five asserts a claim under Section 12(a)(2) of the Securities Act, 15 U.S.C. § 77l(a)(2). Both sections impose civil liability for the making of materially false or misleading statements in registration statements and prospectuses. The Plaintiffs asserting these claims are Kanter and Park East, who purchased Merck stock in the Merck Stock Investment Plan ("MSIP") pursuant to a 2002 Registration Statement, an April 2002 Prospectus and a June 2004 Prospectus (collectively, the "Offering Documents"). They allege that each of the Offering Documents contained materially false and misleading statements, including statements incorporated by reference from other Merck public filings, concerning Vioxx's CV risks and commercial prospects.

A Section 11 claim may be brought against, among others, all persons who signed a registration statement as well as all directors of the company issuing the statement. 15 U.S.C. § 77k(a). Section 12, while similar, targets the person who offers or sells a security, in relevant part, by means of a prospectus which includes a misleading statement or omission of material fact. 15 U.S.C. § 77l(a)(2). Accordingly, in this action, the Director Defendants and various other individuals who signed the 2002 Registration Statement are the targets of the Section 11 claim, and Merck, which issued each of the Offering Documents, is the target of the Section 12 claim.

These claims are not governed by the PSLRA or otherwise subject to a heightened pleading requirement. Moreover, scienter is not an element of the claims. Suprema, 438 F.3d at 269. And while claims under these provisions may be predicated on fraud, they need not be. Id. at 270. Indeed, the Third Circuit has observed that Sections 11 and 12 are "virtually absolute" liability provisions. Id. at 269.

Merck makes three perfunctory arguments for the dismissal of these claims, each of which touch upon deficiencies addressed and rejected earlier in this opinion: Plaintiffs are estopped from claiming that securities laws were violated by Defendants' alleged failure to disclose Vioxx's CV risks and true safety profile, the market was well aware of Vioxx's potential CV risks and the information allegedly misstated or omitted in the Offering Documents was not material. To state a prima facie claim under either Section 11 or Section 12(a)(2) of the Securities Act, a plaintiff need only allege that he purchased a security pursuant to a registration statement (Section 11) or prospectus (Section 12) which contained a material misstatement or omission. Id. at 269-70. The allegations made by Plaintiffs Kanter and Park East in connection with their purchase of Merck common stock through the MSIP clearly satisfy this standard.

B. Section 15 Claim

Count Six asserts a Securities Act control person claim against the Officer Defendants predicated on the alleged violations of Sections 11 and 12(a)(2). Merck does not expressly address this claim in is motion, presumably because it has challenged the sufficiency of the claims related to the predicate violations. As the Court has found that those claims survive this Rule 12(b)(6) motion, it will also permit the Securities Act control person claim to proceed.

CONCLUSION

For the foregoing reasons, the Court grants Merck's motion to dismiss in part and denies it in part. The § 10(b) claim will be dismissed to the extent it is based on alleged misrepresentations made by Merck and/or Defendant Raymond Gilmartin on September 30, 2004. Moreover, the § 10(b) claim will be dismissed without prejudice as to all Defendants on whose behalf Merck moved, except for Merck and Reicin, for failure to meet the pleading requirements of the PSLRA as discussed in Section II.B. The insider trading claim under Exchange Act § 20A will be dismissed without prejudice as to Defendants Gilmartin, Frazier, Lewent, Anstice, Wold-Olsen, Clark and Kelley. In all other respects, Merck's motion to dismiss will be denied. Additionally, Defendant Scolnick's motion to dismiss will be denied in all respects, except as follows: his motion to dismiss the Rule 10b-5 claim will be granted insofar as the claim is based on Merck's 2000 Annual Report, Merck's 2001 Form 10-K and/or Merck's 2002 Registration Statement, and his motion to dismiss the control person claim under §20(a) of the Exchange Act will be granted insofar as the claim is based on misrepresentations post-dating his retirement from Merck.

An appropriate form of Order will be filed.

s/ Stanley R. Chesler
STANLEY R. CHESLER
United States District Judge

Dated: August 8, 2011